

## Package leaflet: Information for the patient

### Royaldee 30 microgram prolonged-release capsules, soft

calcifediol

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Royaldee is and what it is used for
2. What you need to know before you take Royaldee
3. How to take Royaldee
4. Possible side effects
5. How to store Royaldee
6. Contents of the pack and other information

#### 1. What Royaldee is and what it is used for

Royaldee contains the active substance calcifediol, which is a form of vitamin D, which is classified as an anti-parathyroid agent. Royaldee is a “prolonged-release” capsule that releases the active substance slowly.

Royaldee is used to treat **secondary hyperparathyroidism in adults** with chronic kidney disease of stage 3 or 4. This is a disorder where the production of parathyroid hormone (PTH) is increased abnormally.

Parathyroid hormone (PTH) plays an important role in controlling the amount of calcium in bone.

When too much parathyroid hormone is produced by the parathyroid glands, it can cause the loss of calcium from the bones. This can lead to bone pain and fractures. Too much calcium in the blood can cause problems with blood and heart vessels, kidney stones, mental confusion and coma. Royaldee works by controlling the levels of parathyroid hormone in your body.

#### 2. What you need to know before you take Royaldee

##### Do not take Royaldee

- if you are allergic to calcifediol or any of the other ingredients of this medicine (listed in section 6)

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Royaldee if you:

- have or have had high blood levels of calcium or phosphate.  
Symptoms of increased calcium levels include tiredness, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination and weight loss.
- have a liver disease or require dialysis  
Safety and efficacy of Royaldee in patients that require dialysis or have liver disease have not yet been established.

Very low levels of parathyroid hormone over long periods can result in a type of abnormal bone structure. This is known as adynamic bone disease which can only be diagnosed by biopsy. Your parathyroid hormone levels will be monitored during treatment. Your dose of Rayaldee may be reduced if your parathyroid hormone levels become very low.

Your doctor will need to do blood tests to monitor your treatment.

### **Children and adolescents**

Rayaldee is not recommended for children and adolescents under 18 years, as safety and efficacy have not yet been established.

### **Other medicines and Rayaldee**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the action of Rayaldee or make side effects more likely. It is particularly important to tell your doctor if you are taking medicines such as

- ketoconazole, itraconazole, voriconazole: used against fungal infections such as candida or thrush
- clarithromycin, telithromycin: used against bacterial infections
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir: used against HIV infections
- nefazodone: used to treat depression
- cholestyramine: used to lower blood cholesterol levels
- medicines for the heart or to reduce high blood pressure, such as
  - digoxin
  - water pills with active substance names mostly ending with “thiazide” or “tizide”
- phenobarbital or other medicines used to prevent seizures

Your doctor may need to adjust your dose if you are taking medicines containing calcium, vitamin D or water pills. If you are taking a medicine containing digitalis, such as digoxin, your doctor may monitor your calcium more closely and may adjust your dose.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

Do not take Rayaldee without medical supervision. There is no indication that vitamin D is teratogenic in humans at therapeutic doses. Exceeding the recommended dose of Rayaldee (more than 2 capsules per day) over an extended period of time may lead to excessive levels of vitamin D and/or hypercalcemia and may result in physical and mental retardation, among other risks for the baby.

Rayaldee has been prescribed for you only. Always take Rayaldee exactly as your doctor or pharmacist has told you. Ask your doctor or pharmacist if you need more information or advice.

#### Breast-feeding:

Vitamin D and its metabolites are excreted in human milk. This should be considered when giving additional vitamin D to the breastfed child. Your doctor will decide whether to discontinue breast-feeding or Rayaldee treatment.

### **Driving and using machines**

Rayaldee has no or negligible influence on the ability to drive and use machines

### **Royaldee contains sorbitol and ethanol**

This medicine contains 18 mg sorbitol in each capsule, which corresponds to 0.064 mg/mg. This medicine contains 3.944 mg of alcohol (ethanol) in each capsule which is equivalent to 0.014 mg/mg (1.4%w/w). The amount in one capsule of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

### **3. How to take Royaldee**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

#### **The recommended dose is**

- starting dose: 1 capsule once daily
- maximum dose: 2 capsules once daily

Your **doctor** will use the results of your laboratory tests to **decide the correct dose** for you. Once Royaldee treatment starts the doctor will determine whether your dose needs adjusting, based on your response to treatment.

#### **Method of use**

Swallow the capsules whole, with one glass of water, at bedtime, at least 2 hours after any meal.

#### **If you take more Royaldee than you should**

Too much Royaldee can cause abnormally high levels of calcium in the blood, which can be harmful. Symptoms may include feeling tired, difficulty thinking clearly, muscle weakness, irritability, decreased appetite, vomiting, constipation and increased thirst.

Inform your doctor immediately if you have taken too much Royaldee or experience any of these symptoms.

#### **If you forget to take Royaldee**

Do not take a double dose to make up for a forgotten dose. Simply continue to take Royaldee as previously directed (dose and time) by your doctor.

#### **If you stop taking Royaldee**

Do not stop treatment without your doctor's permission. It is important to keep taking Royaldee as your doctor has directed. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects have been reported with following frequencies:

**Common** (may affect up to 1 in 10 people)

- constipation, nausea, diarrhoea
- increased blood levels of calcium, phosphate

**Uncommon** (may affect up to 1 in 100 people)

- dizziness, headache, weakness
- decreased appetite, stomach discomfort
- dry mouth, vomiting

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Rayaldee**

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

Once opened, Rayaldee can be stored for up to 60 days.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Rayaldee contains**

- The active substance is calcifediol. Each capsule contains 30 microgram of calcifediol as calcifediol monohydrate.
- The other ingredients are paraffin hard, paraffin liquid, hypromellose, glycerol monostearate, lauroyl macroglycerides, ethanol anhydrous, butylated hydroxytoluene, modified starch (hydroxypropylstarch), carrageenan, disodium phosphate, anhydrous, sorbitol (E420), liquid, partially dehydrated, Brilliant Blue FCF (E133), titanium dioxide, purified water.

Medium chain triglyceride oil is used as a lubricant during manufacture, and trace amounts may be present in the final formulation.

### **What Rayaldee looks like and contents of the pack**

Rayaldee is provided in a round, plastic bottle with push and turn plastic closure and inner heat-seal liner and thread.

Rayaldee capsules are blue oval soft capsules, 11.7 mm by 6.4 mm.

The pack sizes are 30 capsules or multipack of 90 capsules (3 packs of 30 capsules).

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Vifor Fresenius Medical Care Renal Pharma France  
100–101 Terrasse Boieldieu  
Tour Franklin La Défense 8  
92042 Paris La Défense Cedex  
France

## **Manufacturer**

Vifor France  
100–101 Terrasse Boieldieu  
Tour Franklin La Défense 8  
92042 Paris La Défense Cedex  
France

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Germany:	Royaldee 30 Mikrogramm, Weichkapsel retardiert
Ireland:	Royaldee 30 microgram, prolonged-release capsules, soft
Italy:	Royaldee 30 microgrammi, Capsula molle a rilascio prolungato
Spain	Royaldee 30 microgramos, Cápsula blanda de liberación prolongada
United Kingdom (Northern Ireland)	Royaldee 30 microgram, prolonged-release capsule, soft
Denmark	Royaldee 30 mikrogram, Depotkapsel, blød
Sweden	Royaldee 30 mikrogram, Depotkapsel, mjuk
Norway	Royaldee 30 mikrogram, Depotkapsel, myk
Portugal	Royaldee 30 microgramas, Cápsula mole de libertação prolongada
The Netherlands	Royaldee 30 microgram, zachte capsules met verlengde afgifte

**This leaflet was last revised in 12/2022.**