

## **Package leaflet: Information for the patient**

Paricalcitol Heaton 1 microgram, zachte capsules  
paricalcitol

**Read all of this leaflet carefully before you start using 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 Paricalcitol Heaton is and what it is used for
2. What you need to know before you take Paricalcitol Heaton
3. How to take Paricalcitol Heaton
4. Possible side effects
5. How to store Paricalcitol Heaton
6. Contents of the pack and other information

### **1. What Paricalcitol Heaton is and what it is used for**

Paricalcitol Heaton contains the active substance paricalcitol, which is a synthetic form of active vitamin D.

Active vitamin D is required for the normal functioning of many tissues in the body, including the parathyroid gland and bones. In people who have normal kidney function, this active form of vitamin D is naturally produced by the kidneys, but in kidney failure the production of active vitamin D is markedly reduced. Paricalcitol Heaton therefore provides a source of active vitamin D, when the body cannot produce enough and helps to prevent the consequences of low levels of active vitamin D, namely high levels of parathyroid hormone which can cause bone problems. Paricalcitol Heaton is used in adult patients with kidney disease Stages 3, 4 and 5 and children aged 10 to 16 years with kidney disease Stages 3 and 4.

### **2. What you need to know before you take Paricalcitol Heaton**

#### **Do not take Paricalcitol Heaton**

- If you are allergic to paricalcitol or any of the other ingredients of this medicine (listed in section 6).
- If you have very high levels of calcium or vitamin D in your blood.

Your doctor will be able to tell you if these conditions apply to you.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Paricalcitol Heaton

- before the treatment begins, it is important to limit the amount of phosphorus in your diet.
- phosphate-binding medicines may be needed to control phosphorus levels. If you are taking calcium-based phosphate binders, the doctor may need to adjust your dose.

- your doctor will need to do blood tests to monitor your treatment.
- in some patients with chronic kidney disease stages 3 and 4, an increase in the blood levels of creatinine has been observed. However, this increase does not reflect a reduction in renal function.

### **Other medicines and Paricalcitol Heaton**

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

Some medicines may affect the action of this medicine or may increase the likelihood of side-effects. It is particularly important to tell your doctor if you are taking any of the following medicines:

- to treat fungal infections such as candida or thrush (for example ketoconazole);
- to treat heart problems or high blood pressure (for example digoxin, diuretics or water pills);
- that contain a source of phosphate (for example, medicines to lower calcium levels in the blood);
- that contain calcium or Vitamin D, including supplements and multivitamins that can be bought without a prescription;
- that contain magnesium or aluminium (for example some types of indigestion medicines (antacids) and phosphate-binders);
- to treat elevated cholesterol levels (for example cholestyramine).

### **Paricalcitol Heaton with food and drink**

Paricalcitol Heaton can be taken with or without food.

### **Pregnancy, breast-feeding and fertility**

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.

There is no adequate data on the use of paricalcitol in pregnant women. Potential risk in human use is not known, therefore paricalcitol should not be used unless clearly necessary.

It is not known if paricalcitol passes into human breast milk. Tell your doctor before breast-feeding while taking Paricalcitol Heaton.

### **Driving and using machines**

Paricalcitol Heaton should not affect your ability to drive or use machines.

### **Paricalcitol Heaton contains ethanol (alcohol)**

This medicine contains a small amount of ethanol (an alcohol), less than 100mg per capsule, which may modify or increase the effect of other medicines. This could be harmful to people who suffer from liver disease, alcoholism, epilepsy, brain injury or disease as well as in pregnant or breast-feeding women and children.

### **3. How to take Paricalcitol Heaton**

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

#### **Chronic Kidney Disease Stages 3 and 4**

In adult patients the usual initial dose is one capsule every day, or every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Paricalcitol Heaton is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Paricalcitol Heaton for you.

#### **Chronic Kidney Disease Stage 5**

In adult patients the usual initial dose is one capsule every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Paricalcitol Heaton is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Paricalcitol Heaton for you.

#### **Liver disease**

If you have mild to moderate liver disease, your dose will not need to be adjusted. However, there is no experience in patients with severe liver disease.

#### **Renal transplant**

The usual dose is one capsule every day, or every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Paricalcitol Heaton is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Paricalcitol Heaton for you.

#### **Use in children and adolescents**

In children ages 10 to 16 years of age with chronic kidney disease Stages 3 or 4 the usual initial dose is one capsule every other day, up to three times a week. Your doctor will use the results of your laboratory tests to decide the correct dose for you. Once Paricalcitol Heaton is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose of Paricalcitol Heaton for you.

The efficacy of Paricalcitol Heaton in children with CKD Stage 5 has not been established. Paricalcitol Heaton in children under the age of 10 years.

#### **Use in elderly**

There is a limited amount of experience of using Paricalcitol Heaton in patients aged 65 years or older. In general no overall differences in effectiveness or safety were seen between patients aged 65 years or older and younger patients.

#### **If you take more Paricalcitol Heaton than you should**

Too much Paricalcitol Heaton can cause abnormally high levels of calcium in the blood, which can be harmful. Symptoms which can appear soon after taking too much Paricalcitol Heaton may include a feeling of weakness and/or drowsiness, headache, nausea (feeling sick) or vomiting (being sick), a dry mouth, constipation, pains in muscles or bones and a metallic taste in the mouth.

Symptoms which can develop over a longer period of taking too much Paricalcitol Heaton include loss of appetite, drowsiness, weight loss, sore eyes, a runny nose, itchy skin, feeling hot and feverish, loss of sex drive and severe abdominal pain (due to an inflamed pancreas) and kidney stones. Your blood pressure may be affected and heart beat irregularities (palpitations) can occur. The results of blood and

urine tests may show high cholesterol, urea, nitrogen and raised levels of liver enzymes. Paricalcitol Heaton may rarely cause mental changes including confusion, drowsiness, insomnia or nervousness.

If you take too much Paricalcitol Heaton, or experience any of the above, seek medical advice immediately.

### **If you forget to take Paricalcitol Heaton**

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the dose that you have missed, simply continue to take Paricalcitol Heaton as previously directed (dose and time) by your doctor.

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Paricalcitol Heaton**

Unless your doctor tells you to stop your treatment, it is important to keep taking Paricalcitol Heaton 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.

### **Important: Tell your doctor immediately if you notice any of the following side effects:**

- allergic reactions (such as shortness of breath, wheezing, rash, itching, or swelling of the face and lips)

Tell your doctor if you notice any of the following side effects:

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

- increase in the blood levels of calcium, as well as the amount of calcium times phosphate (in patients with significant chronic kidney disease)
- phosphate blood levels may also be increased

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

- pneumonia (lung infection)
- decreased levels of parathyroid hormone
- decreased appetite
- decreased levels of calcium
- dizziness
- unusual taste in the mouth
- headache
- irregular heartbeat
- stomach discomfort or pain
- constipation
- diarrhoea
- dry mouth
- heartburn (reflux or indigestion)
- nausea
- vomiting

- acne
- itchy skin
- rash
- hives
- muscle cramps
- muscle pain
- breast tenderness
- weakness
- feeling tired, not feeling well
- swelling in the legs
- pain
- increased levels of creatinine
- changes in liver function tests

If you experience an allergic reaction, please contact your doctor immediately.

### **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 will help provide more information about the safety of this medicine.

## **5. How to store Paricalcitol Heaton**

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and label 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 to protect the environment.

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

### **What Paricalcitol Heaton contains**

- The active substance is paricalcitol. Each soft capsule contains 1 microgram of paricalcitol.
- The other ingredients are: medium chain triglycerides, ethanol, butylhydroxytoluene (E321).
- The capsule shell contains: gelatin (E441), glycerol (E442), titanium dioxide (E171), iron oxide black (E172).

### **What Paricalcitol Heaton looks like and contents of the pack**

Paricalcitol Heaton 1 microgram capsules, is an oval, grey soft capsule, containing a clear solution.

Packaging: Carton box containing 7 caps, 28 caps or 30 caps.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

HEATON k.s.  
Na Pankráci 332/14  
140 00 Praag 4  
Tsjechië

**Manufacturer:**

GAP S.A.  
Agissilaou str. 46  
173 41 Agios Dimitrios, Athene  
Griekenland

RAFARM S.A.  
Thesi Pousi Xatzi Agiou Louka  
19002, Paiania, Athene  
Griekenland

**In het register ingeschreven onder:**

RVG 130843

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

Czech Republic	Paricalcitol
Slovak Republic	Paricalcitol Heaton 1 mikrogram mäkké kapsuly
Romania	Paricalcitol Heaton 1 microgram, capsule moi
The Netherlands	Paricalcitol Heaton 1 microgram, zachte capsules

**Deze bijsluiter is voor het laatst goedgekeurd in juli 2025**