**Package leaflet: Information for the patient**

**Porontazin 1 microgram, zachte capsules**
**Porontazin 2 microgram, zachte capsules**

paricalcitol

**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 Porontazin is and what it is used for

Porontazin 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. Porontazin 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. Porontazin 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 Porontazin

**Do <u>not</u> take Porontazin:**
- if you are **allergic** to paricalcitol or to 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 Porontazin

- 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 a substance called creatinine has been observed. However, this increase does not reflect a reduction in renal function.

**Contact you doctor or pharmacist if you have any questions about taking Porontazin.**

**Other medicines and Porontazin**
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 Porontazinthis 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)

**Porontazin with food and drink**
Porontazin may 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 Porontazin.

**Driving and using machines**
Porontazin should not affect your ability to drive or use machines

**Porontazin contains ethanol 96%.**
1 µg: This medicine contains 0.7 mg of alcohol (ethanol) in each capsule.
2 µg: This medicine contains 1.4 mg of alcohol (ethanol) in each capsule.
The amount in one capsule of this medicine is equivalent to less than 0 ml beer or 0 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

## 3. How to take Porontazin

Always take Porontazinthis 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 Porontazin

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 Porontazin 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 Porontazin 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 Porontazin 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. OncePorontazin is started, the dose is likely to need adjusting, depending on how you respond to treatment. Your doctor will help determine the correct dose ofPorontazin 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 Porontazin 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 Porontazin for you.
The efficacy of Porontazin in children with CKD Stage 5 has not been established.
There is no information on the use of Porontazin capsules in children under the age of 10 years.

**Use in elderly**
There is a limited amount of experience of using Porontazin 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 Porontazin than you should**
Too much Porontazin can cause abnormally high levels of calcium in the blood, which can be harmful. Symptoms which can appear soon after taking too much Porontazin 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 Porontazin 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. Porontazin may rarely cause mental changes including confusion, drowsiness, insomnia or nervousness.

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

**If you forget to take Porontazin**
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 Porontazin 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 Porontazin**

Unless your doctor tells you to stop your treatment, it is important to keep taking Porontazin 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 or nurse if you notice any of the following side effects:
**Common side effects** *(these may affect up to 1 in 10 patientsPorontazin:*
- increase in the blood levels of a substance called calcium, as well as the amount of calcium times the amount of another substance in the blood called phosphate (in patients with significant chronic kidney disease)
- phosphate blood levels also may be increased

**Uncommon side effects** *(these may affect up to 1 in 100 patientsPorontazin):*
- 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.
*PorontazinPorontazinPorontazin*
**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 Nederlands Bijwerkingen Centrum Lareb, Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Porontazin

Don't store Porontazin above 30°C.

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

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

## 6. Contents of the pack and other information

**What Porontazin contains**

- The active substance is paricalcitol. Each soft capsule contains 1 microgram paricalcitol.
  Each soft capsule contains 2 micrograms paricalcitol
- The other ingredients are
- inside the capsule: Triglycerides, medium chain, ethanol 96% and butylhydroxytoluene (E321)
- capsule shell: 1 mcg: Gelatin (E441), purified water, glycerol (E422), titanium dioxide (E171)
  2 mcg: Gelatin (E441), purified water, glycerol (E422), titanium dioxide (E171), iron oxide red (E172)

**What Porontazin looks like and contents of the pack**

Porontazin 1 microgram are white to off-white, oval, soft-gelatin capsules containing a clear oily liquid.
Porontazin 2 microgram are red, oval, soft-gelatin capsules containing a clear oily liquid.
They are available in packs of 7, 28 and 30 capsules. Not all pack sizes may be available.

**Marketing Authorisation Holder and Manufacturer**

Regiomedica GmbH
Spitalstr. 22
79539 Lörrach
Germany

Porontazin 1 microgram is registered under RVG 113731
Porontazin 2 microgram is registered under RVG 113732

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| Netherlands | Porontazin 1 microgram zachte capsules |
| | Porontazin 2 microgram zachte capsules |
| Luxembourg | Porontazin 1 Mikrogramm Weichkapseln |
| | Porontazin 2 Mikrogramm Weichkapseln |

**This leaflet was last revised in November 2020**.