Package leaflet: Information for the patient

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Mimpara 30 mg film-coated tablets
Mimpara 60 mg film-coated tablets
Mimpara 90 mg film-coated tablets
Cinacalcet

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mimpara is and what it is used for

Mimpara works by controlling the levels of parathyroid hormone (PTH), calcium and phosphorous in your body. It is used to treat problems with organs called parathyroid glands. The parathyroids are four small glands in the neck, near the thyroid gland, that produce parathyroid hormone (PTH).

Mimpara is used:
- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products.
- to reduce high levels of calcium in the blood (hypercalcaemia) in patients with parathyroid cancer.
- to reduce high levels of calcium in the blood (hypercalcaemia) in patients with primary hyperparathyroidism when removal of the gland is not possible.

In primary and secondary hyperparathyroidism too much PTH is produced by the parathyroid glands. "Primary" means that the hyperparathyroidism is not caused by any other condition and "secondary" means that the hyperparathyroidism is caused by another condition, e.g., kidney disease. Both primary and secondary hyperparathyroidism can cause the loss of calcium in the bones, which can lead to bone pain and fractures, problems with blood and heart vessels, kidney stones, mental illness and coma.

2. What you need to know before you take Mimpara

Do not take Mimpara:
- If you are allergic to cinacalcet or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Mimpara.

Before you start taking Mimpara, tell your doctor if you have or have ever had:
- **seizures** (fits or convulsions). The risk of having seizures is higher if you have had them before;
- **liver problems**;
- **heart failure.**

Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in patients treated with Mimpara.

Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heartbeat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking Mimpara.

For additional information see section 4.

During treatment with Mimpara, tell your doctor:
- if you start or stop smoking, as this may affect the way Mimpara works.

Children and adolescents
Children under the age of 18 must not take Mimpara.

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

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how Mimpara works:
- medicines used to treat **skin** and **fungal infections** (ketoconazole, itraconazole and voriconazole);
- medicines used to treat **bacterial infections** (telithromycin, rifampicin and ciprofloxacin);
- a medicine used to treat **HIV** infection and AIDS (ritonavir);
- a medicine used to treat **depression** (fluvoxamine).

Mimpara may affect how medicines such as the following work:
- medicines used to treat **depression** (amitriptyline, desipramine, nortriptyline and clomipramine);
- medicines used to treat **changes in heart rate** (flecainide and propafenone);
- a medicine used to treat **high blood pressure** (metoprolol).

Mimpara with food and drink
Mimpara should be taken with or shortly after 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.

Mimpara has not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as Mimpara might harm the unborn baby.

It is not known whether Mimpara is excreted in human milk. Your doctor will discuss with you if you should discontinue either breast-feeding or treatment with Mimpara.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. Dizziness and seizures have been reported by patients taking Mimpara. If you experience these, your ability to drive or operate machinery may be affected.

Mimpara contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Mimpara

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure. Your doctor will tell you how much Mimpara you must take.

Mimpara must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be divided.

Your doctor will take regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

<u>If you are being treated for secondary hyperparathyroidism</u>
The usual starting dose for Mimpara is 30 mg (one tablet) once per day.

<u>If you are being treated for parathyroid cancer or primary hyperparathyroidism</u>
The usual starting dose for Mimpara is 30 mg (one tablet) twice per day.

If you take more Mimpara than you should
If you take more Mimpara than you should you must contact your doctor immediately. Possible signs of overdose include numbness or tingling around the mouth, muscle aches or cramps and seizures.

If you forget to take Mimpara
Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of Mimpara, you should take your next dose as normal.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

If you start to get numbness or tingling around the mouth, muscle aches or cramps and seizures **you should tell your doctor immediately.** These may be signs that your calcium levels are too low (hypocalcaemia).

Very common: may affect more than 1 in 10 people
- nausea and vomiting, these side effects are normally quite mild and do not last for long.

Common: may affect up to 1 in 10 people
- dizziness
- numbness or tingling sensation (paraesthesia)
- loss (anorexia) or decrease of appetite
- muscle pain (myalgia)
- weakness (asthenia)
- rash
- reduced testosterone levels
- high potassium levels in the blood (hyperkalaemia)
- allergic reactions (hypersensitivity)
- headache
- seizures (convulsions or fits)
- low blood pressure (hypotension)
- upper respiratory infection
- breathing difficulties (dyspnoea)
- cough
- indigestion (dyspepsia)
- diarrhoea
- abdominal pain, abdominal pain – upper
- constipation
- muscle spasms
- back pain
- low calcium levels in the blood (hypocalcaemia).

Not known: frequency cannot be estimated from available data
- Hives (urticaria)
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Unusually fast or pounding heart beat which may be associated with low levels of calcium in your blood (QT prolongation and ventricular arrhythmia secondary to hypocalcaemia).

After taking Mimpara a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

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Children and adolescents
The use of Mimpara in children and adolescents has not been established. A fatal outcome was reported in an adolescent clinical trial patient with very low calcium levels in the blood (hypocalcaemia).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mimpara

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 ºC.

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 Mimpara contains
- The active substance is cinacalcet. Each film-coated tablet contains 30 mg, 60 mg or 90 mg of cinacalcet (as hydrochloride).
- The other ingredients are:
  - Pre-gelatinised maize starch
  - Microcrystalline cellulose
  - Povidone
  - Crospovidone
  - Magnesium stearate
  - Colloidal anhydrous silica
- The tablets are coated with:
  - Carnauba wax
  - Opadry green (containing lactose monohydrate, hypromellose, titanium dioxide (E171), glycerol triacetate, FD&C Blue (E132), iron oxide yellow (E172))
  - Opadry clear (containing hypromellose, macrogol)

What Mimpara looks like and contents of the pack
Mimpara is a light green film-coated tablet. They are oval-shaped and have "30", "60" or "90" marked on one side and "AMG" on the other side.

Mimpara is available in blisters of 30 mg, 60 mg or 90 mg film-coated tablets. Each blister pack contains either 14, 28 or 84 tablets in a carton.

Not all pack sizes may be marketed.

Site of Manufacture of the Drug Product:
Amgen Manufacturing Limited
State Road 31
Kilometer 24.6
Juncos 00777-4060
Puerto Rico
USA

Marketing Authorisation Holder and Manufacturer:
Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

This leaflet was last revised in August 2015.

THIS MEDICINE

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicines out or reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.