Package leaflet: Information for the patient

Mimpara 1 mg granules in capsules for opening
Mimpara 2.5 mg granules in capsules for opening
Mimpara 5 mg granules in capsules for opening
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 in adults:
- to treat secondary hyperparathyroidism in adults 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 adult patients with parathyroid cancer.
- to reduce high levels of calcium in the blood (hypercalcaemia) in adult patients with primary hyperparathyroidism when removal of the gland is not possible.

Mimpara is used in children aged 3 years to less than 18 years of age:
- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products, whose condition is not controlled with other treatments.

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).

Do not take Mimpara if you have low levels of calcium in your blood. Your doctor will monitor your blood calcium levels.

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.**

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

Please tell your doctor if you experience any of the following which may be signs of low calcium levels: spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes or around your mouth or seizures, confusion or loss of consciousness while being 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 with parathyroid cancer or primary hyperparathyroidism must not take Mimpara.

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with Mimpara and during treatment with Mimpara. You should inform your doctor if you experience any of the signs of low calcium levels as described above.

It is important that you take your dose of Mimpara as advised by your doctor.

Other medicines and Mimpara
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly etelcalcetide or any other medicines that lower the level of calcium in your blood.

You should not receive Mimpara together with etelcalcetide.

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);

- a medicine used to relieve **cough** (dextromethorphan);
- 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
Dizziness and seizures have been reported by patients taking Mimpara. If you experience these side effects, do not drive or operate machines

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.

Do not swallow the capsules whole. You must open the capsules and administer the entire content of granules. For instructions on how to use Mimpara granules, read the section at the end of this leaflet.

Different strengths of granules should not be mixed, in order to avoid dosing errors.

The granules should be taken with or shortly after food

Mimpara is also available as tablets. Children who require doses of 30 mg or more and who are able to swallow tablets may receive Mimpara tablets.

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

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

The usual starting dose of Mimpara for children aged 3 years to less than 18 years of age is no more than 0.20 mg/kg of body weight daily.

If you are being treated for parathyroid cancer or primary hyperparathyroidism
The usual starting dose for Mimpara in adults 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.

Please tell your doctor immediately:

- If you start to get numbness or tingling around the mouth, muscle aches or cramps and seizures. These may be signs that your calcium levels are too low (hypocalcaemia).
- If you experience swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).

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).

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 bottle. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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.

Do not store Mimpara mixed with food or liquid.

6. Contents of the pack and other information

What Mimpara contains

- The active substance is cinacalcet. Each capsule contains 1 mg, 2.5 mg or 5 mg of cinacalcet (as hydrochloride) granules.
- The other ingredients of the granules are:
  - Pre-gelatinised maize starch
  - Microcrystalline cellulose
  - Povidone
  - Crospovidone
  - Silica, dental type

- The capsule shell contains:
  - Printing ink: iron oxide black, shellac, propylene glycol
  - Gelatin
  - Iron oxide yellow (E172) (1 mg and 2.5 mg capsules)
  - Indigo carmine (E132) (1 mg and 5 mg capsules)
  - Titanium dioxide (E171) (1 mg, 2.5 mg and 5 mg capsules)

What Mimpara looks like and contents of the pack
Mimpara granules are white to off-white in appearance and are presented in capsules for opening. The capsules have a white body and coloured caps “1 mg” (dark green cap), “2.5 mg” (yellow cap) or “5 mg” (blue cap) marked on one side and “AMG” on the other side.

Mimpara is available in bottles of 1 mg, 2.5 mg or 5 mg capsules, inside a carton. Each bottle contains 30 capsules.

Marketing Authorisation Holder
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Milton Road
Cambridge
CB4 0WA
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Manufacturer
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The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Amgen Limited
Tel: +44 (0)1223 420305

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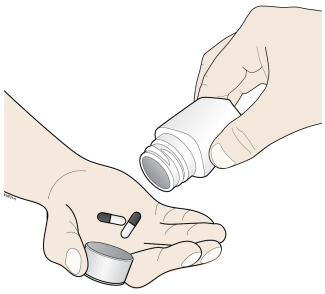
Instructions for taking Mimpara granules

Only the granules should be swallowed. The capsule shell is not for ingestion.

You should take the granules with food or liquid. For patients who cannot swallow, you can administer the granules through a tube into the stomach ("nasogastric" or "gastrostomy" tubes, made of polyvinylchloride) in a small amount of water (at least 5 mL).

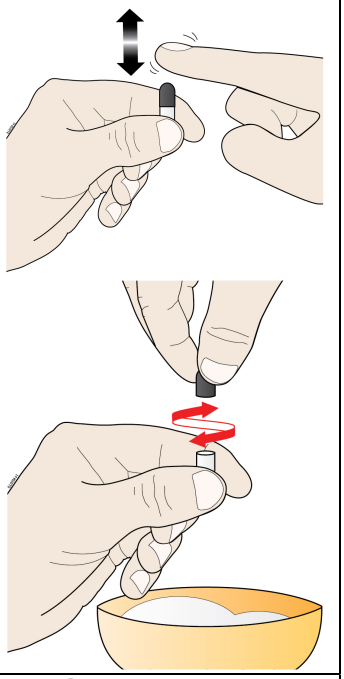
For patients that can swallow you will need:
A small bowl, cup or spoon with soft food (such as apple sauce or yogurt) or liquid (such as apple juice or renal infant formula). Using water is not recommended as it may make the medicine taste bitter. The amount of food you use will depend on how many capsules you need to use every day:

- 1 to 3 capsules a day use at least 1 tablespoon (15 mL)
- 4 to 6 capsules a day use at least 2 tablespoons (30 mL)

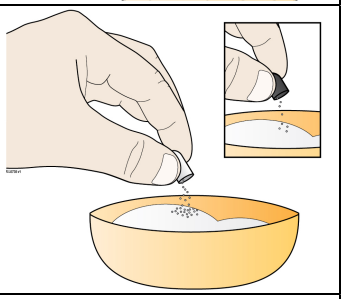
• Wash your hands thoroughly with soap and water. • Check that you have the correct strength of capsules. • Over a clean work surface remove from the bottle the number of capsules your doctor or pharmacist told you to use. • Do not mix granules of different strengths to avoid incorrect dosing.	

To open the capsule:

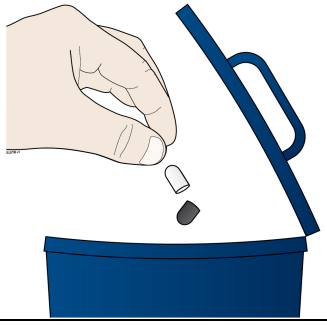
- Hold each capsule upright (with the coloured cap on top).
- Tap the capsule gently so the contents settle on the bottom of the capsule (white part of capsule).
- Hold the capsule upright over the soft food or liquid.
- Gently squeeze the top and twist slightly to remove, taking care not to spill the contents.



- Empty the entire contents of the bottom of the capsule onto the food or liquid.
- Make sure remaining content from the top is also emptied on the food or liquid.



Dispose of the capsule shells.



Take all food or liquid immediately. If you used food to take Mimpara granules, drink something afterwards to make sure all the medicine is swallowed.