Information for adult patients prescribed Mimpara® (cinacalcet) tablets

AMGEN®
Nephrology

IE-MPA-2000002 Date of Preparation: April 2020

Renal Clinic Information

Doctor's Name:

Tel No:

Nurse's Name:

Tel No:

Dietician's Name:

Tel No:

Your doctor has prescribed Mimpara® tablets

This leaflet has been given to you because you have been prescribed Mimpara® (cinacalcet) for the treatment of your secondary hyperparathyroidism (SHPT).

This leaflet contains information to help you to understand why you have been prescribed Mimpara® and how to take it.

You should also read the patient information that can be found inside your Mimpara® pack or at www.medicines.ie/medicines/mimpara-tablets-32867/patient-info

If you have any further questions, or feel unsure about any aspect of your treatment, please speak to your doctor, renal nurse or pharmacist.

Your doctor has prescribed Mimpara® tablets to treat your secondary hyperparathyroidism (SHPT)

What is SHPT?
SHPT can occur if your kidneys are not working properly. If you have SHPT, your body is making too much of a hormone known as parathyroid hormone (PTH).

- PTH is made in four small glands, found in the neck, called the parathyroid glands.
- You need normal levels of PTH to have the right amounts of calcium and phosphate in your blood. This keeps your bones, heart, muscles, nerves and blood vessels healthy.
- People with SHPT have high levels of PTH. This changes calcium and phosphate levels in the blood and can have serious effects.
- In SHPT, 'secondary' means that the over production of PTH is caused by another condition, that is your kidney disease.

What are the symptoms of SHPT?
Some people with SHPT do not have any symptoms, but others may have problems such as:

- Itchy skin (pruritus);
- "Pins and needles" in the face, hands or feet;
- Pain, especially bone pain;
- Muscle weakness.

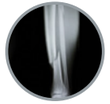
If you experience these or any other symptoms, talk to your healthcare team.

AMGEN Nephrology

What can happen if PTH levels are too high?

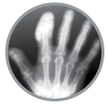
If your PTH, calcium and phosphorous levels are not kept within normal levels, there can be serious effects.

If PTH levels are too high, you may need surgery to remove all or part of your parathyroid glands.



You may be more likely to suffer from broken bones because your bones are more brittle.

You may be more likely to suffer from problems with your heart and blood vessels like high blood pressure or heart attack.



Calcium may build up in other parts of your body which can be painful.

Because of these effects, it is very important that SHPT is treated.

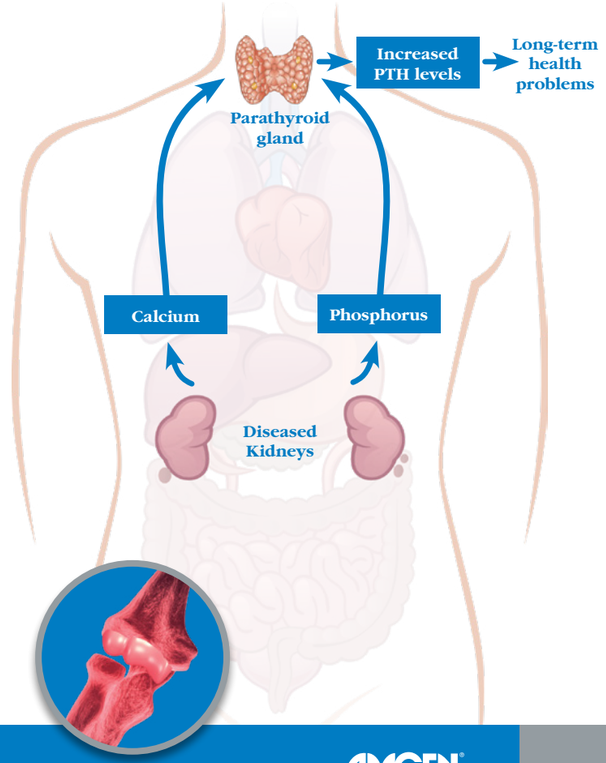
For people with SHPT, what happens when their kidneys are damaged?

Kidneys
When kidneys are not working properly, calcium levels go down and phosphate levels go up in the blood.

Parathyroid glands
The parathyroid glands are then switched on, and PTH goes up.

Bones
When the PTH level is high, your bones lose calcium and phosphate. This can be harmful to your bones.

If you need more detailed information about SHPT, please speak to your doctor.



AMGEN
Nephrology

How is SHPT treated?

SHPT needs to be treated to control your PTH levels. Treatment may include a low phosphate diet and medication.

Your doctor has a number of drug treatment options available to treat your SHPT. Mimpara® is one of them.

You may have regular blood tests to find out how well your treatment is working and if any changes are needed.

How does Mimpara® work?

Mimpara® works by lowering the levels of PTH, calcium and phosphorus in your blood.

It is important for dialysis patients to reach target levels for PTH, calcium and phosphorus and to keep them within a healthy range. Mimpara® may help to do this.

What is Mimpara®?

Mimpara® is a tablet for adults on kidney dialysis who are suffering from SHPT.

Mimpara® is a small, light-green tablet which has AMG marked on one side and 30, 60 or 90 on the other side. This is because Mimpara® comes in three different strengths.

Mimpara® may be given to you with other medicines to treat your SHPT. The active ingredient in Mimpara® is cinacalcet. Mimpara® also contains lactose as an inactive ingredient. If you have been told by your doctor that you have intolerance to some sugars, you should speak to your doctor before taking Mimpara®.

How should I store my Mimpara®?

Your Mimpara® should be stored at normal room temperature and within its original packaging.

Keep your Mimpara® out of the sight and reach of children.

Do not use your Mimpara® after the expiry date which is printed on the box and the blister pack. The expiry date refers to the last day of the month shown.

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

How should I take Mimpara®?

It is important to take Mimpara® exactly as your doctor or pharmacist has told you.

Your doctor will tell you the dose of Mimpara® you must take. You should take your tablet(s) once a day. Each tablet should be swallowed whole and not chewed, crushed or divided. Check with your doctor or pharmacist if you are unsure.

Mimpara® should be taken at the same time every day. You should take your Mimpara® with, or shortly after, food. Taking Mimpara® after 6pm may help reduce side effects such as feeling or being sick.

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

Even if you feel well, it is important that you continue to take your Mimpara®.

Do not pass your Mimpara® tablets on to anybody else.

What should I do if I forget to take my Mimpara®?

If you forget to take your Mimpara®, you should just take your next dose as normal.

DO NOT take a double dose to make up for a forgotten dose.
If you have any concerns about missed doses, or any further questions on the use of Mimpara®, you should speak to your doctor, pharmacist or nurse.

What if I take more Mimpara® than I 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.

What do I need to know before and during treatment with Mimpara®?

Mimpara® reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported 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®**. 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. Please read the patient information leaflet for a list of possible interactions.

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

What are the most common side effects of Mimpara®?

Like all medicines, Mimpara® can cause side effects, although not everybody gets them.
Possible side effects associated with Mimpara® include:

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).

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).

This is not a complete list of possible side effects. Please read the patient information leaflet found in your Mimpara® pack or at www.medicines.ie/medicines/mimpara-tablets-32867/patient-info.
If you have any questions or concerns about side effects you should talk to your doctor, pharmacist or renal nurse.

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®.

Dizziness and seizures have been reported by patients taking Mimpara®. If you experience these side effects, do not drive or operate machines.

Where can I find more information?

You should always read the patient information leaflet found in your Mimpara® pack or at www.medicines.ie/medicines/mimpara-tablets-32867/patient-info.
If you have any questions about your kidney disease, your SHPT, your treatment (including Mimpara®) or your diet, speak to your doctor, renal nurse, pharmacist or dietician.

Patient Support Organisations

Republic of Ireland
Irish Kidney Association
Donor House, Block 43A,
Parkwest, Dublin 12 D12 P5V6
Tel: 01-6205306 | www.ika.ie

United Kingdom
National Kidney Federation
The Point, Coach Road, Shireoaks,
Worksop, Notts S81 8BW
Tel: 01909 544999

Kidney Care UK
3 The Windmills, Turk Street, Alton,
Hants GU34 1EF
Tel: 01420 541424

Kidney Research UK
Nene Hall, Lynch Wood Park,
Peterborough PE2 6FZ
Tel: 0300 303 1100

Date of next SHPT blood tests:

Test type: Date Due:

Test type: Date Due:

Test type: Date Due:

Test type: Date Due:

Test type: Date Due:

Test type: Date Due:

Test type: Date Due:

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 the patient leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160. By reporting side effects you can help provide more information on the safety of this medicine.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

IE-MPA-2000002 Date of preparation: April 2020

©2020 Amgen Inc. All rights reserved.
Amgen Ireland Ltd, 21 Northwood court, Santry, Dublin 9, Ireland

AMGEN®
Nephrology