Patient leaflet in accordance with the Pharmacists' Regulation (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only.

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

Active Ingredient
Each film-coated tablet contains 30 mg, 60 mg or 90 mg of cinacalcet (as hydrochloride).

For Inactive ingredients and allergens in the medicine – see section 6 "Additional Information''. Read this leaflet carefully and until the end before using this medicine.
This leaflet contains essential information about the medicine. If you have additional questions, contact your doctor or pharmacist.

This medicine is prescribed for treating your illness. Do not pass it on to others. It may cause them harm even if it appears to you that their illness is similar.

This medicine is not for use in children and adolescents under 18 years of age.

1. What is this medicine intended for?

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.

Therapeutic group: Mimpara is a calcimimetic agent.

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).

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. Before using this medicine

X Don't use this medicine if:
- you are sensitive (allergic) to the active material or to any of the additional ingredients in this medicine (refer to list of inactive ingredients)

! Special warnings regarding the usage of the medicine
Talk to your doctor, pharmacist or nurse before taking Mimpara.

! Before treatment with Mimpara, tell the doctor if you suffer or have ever suffered:

- **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 heart beat, 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 “Side Effects’’.

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.

! **If you are taking or have lately taken other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist**. In particular, you should inform the doctor or pharmacist if you are taking:

Medicines that can affect the activity of Mimpara:

- 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 the activity of the following medicines:

- 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).

! Taking Mimpara and food
Mimpara should be taken with or shortly after food.

! Pregnancy and breast-feeding
Consult the doctor or pharmacist before using the medicine.

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.

! Important information on part of the medicine ingredients

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

3. How to Use This Medicine?

Always use this medicine in accordance with a doctor's instructions.

Check with a doctor or a pharmacist if you are not sure.

The dosage and treatment will be determined by the doctor only. The usually accepted dosage is:

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

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

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

Tests and follow-up
Your doctor will request regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

If you accidentally took a higher dose, or if a child accidentally swallowed the medicine, go to a doctor or a hospital emergency room immediately, bringing the packaging of the medication with you.
Possible signs of overdose include numbness or tingling around the mouth, muscle aches or cramps and seizures.

If you forgot to take the medicine 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.

Treatment should persist in accordance with the doctor's recommendations.

If you stop treatment with the medicine
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting first with the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if needed.

If you have any additional questions regarding the usage of this medicine, consult a doctor or a pharmacist.

4. Side Effects

Like any medicine, using Mimpara may cause side effects in some of the users. It is possible that you will not suffer from any one of them.

Contact a doctor immediately if you experience the following side effects:

- numbness or tingling around the mouth
- muscle aches
- cramps
- seizures.

These may be signs that your calcium levels are too low (hypocalcaemia).

Additional side effects

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 difficulties 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 blood hypocalcaemia)

After taking Mimpara, a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension). If a side effect appears, or gets more severe, or if you suffer from a side effect that is not mentioned in the leaflet, consult with the doctor.

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).

You may report side effects to the Ministry of Health, via the on line adverse event form located at the MoH home site: www.health.gov.il
Or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic
@moh.gov.il

5. How to Store the Medicine?

- Avoid toxicity! This medicine and any other medicine should be stored in a closed place, out of the reach of children and/or infants, thereby preventing toxicity. Do not cause vomiting without an explicit instruction from a doctor.
- Don't take medicines in the dark! Check the label and dosage every time that you take medicine. Put on your glasses if you need them.
- Don't use this medicine after the expiry date (EXP) that appears on the package and blister. The expiry date refers to the last day of that particular month.
- Store this product in a cool and dry place.
- Store in the original package
- 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. Additional Information

In addition to the active ingredient, this medicine also contains:

- Pregelatinized Starch
- Microcrystalline Starch
- Povidone
- Crospovidone
- Magnesium Stearate
- Colloidal Anhydrous Silica

The tablets are coated with:

- Carnauba Wax
- Opadry II green: (Lactose monohydrate, hypromellose, titanium dioxide (E171), glycerol triacetate, FD&C Blue (E132), iron oxide yellow (E172))
- Opadry clear: (Hypromellose, macrogol)

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 medicine.

- Each 30 mg tablet contains 2.74 mg of lactose
- Each 60 mg tablet contains 5.47 mg of lactose
- Each 90 mg tablet contains 8.21 mg of lactose

How the medicine looks and what is the content of the package?
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.

Registration Holder's name and address
Amgen Europe B.V.
P.O. BOX 53313, Tel - Aviv

Manufacturer's name and address:
Amgen Europe B.V.
Minervum 7061 Breda the Netherlands

This leaflet was checked and approved by the Ministry of Health on the date: May 2017.

Registration number of the medicine in the National Drugs Registry at the Ministry of **Health**

Mimpara 30	137-29-31506-00
Mimpara 60	137-30-31507-00
Mimpara 90	137-31-31508-00

For simplicity and ease of reading, this leaflet has been written in the masculine form. Nonetheless, this medication is intended for both sexes.