

## **Package leaflet: Information for the patient**

**Cinacalcet Aristo 30 mg, filmomhulde tabletten**  
**Cinacalcet Aristo 60 mg, filmomhulde tabletten**  
**Cinacalcet Aristo 90 mg, filmomhulde tabletten**

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 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 [product name] is and what it is used for
2. What you need to know before you take [product name]
3. How to take [product name]
4. Possible side effects
5. How to store [product name]
6. Contents of the pack and other information

### **1. What [product name] is and what it is used for**

[Product name] 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).

[Product name] 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.

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 [product name]**

**Do not take [product name],**

- if you are allergic to cinacalcet or any of the other ingredients of this medicine (listed in section 6);
- 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 or pharmacist before taking [product name].

Before you start taking [product name], 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.

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

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 [product name].

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 [product name].

For additional information see section 4.

During treatment with [product name], tell your doctor,

- if you start or stop smoking, as this may affect the way [product name] works.

## Children and adolescents

Children under the age of 18 must not take [product name].

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with [product name] and during treatment with [product name]. 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 [product name] as advised by your doctor.

## Other medicines and [product name]

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

### Medicinal products known to reduce serum calcium

You should not receive [product name] together with etelcalcetide, as there is an increased risk of a condition called hypocalcaemia, when [product name] is taken together with medicinal products, that are known to reduce calcium levels in your blood.

Tell your doctor if you are taking the following medicines.

### Medicines such as these can affect how [product name] 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)

### [product name] 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)

#### **[Product name] with food and drink**

[Product name] 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.

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

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

#### **Driving and using machines**

Dizziness and seizures have been reported by patients taking [product name]. If you experience these side effects, do not drive or operate machines.

#### **[Product name] 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.

#### **[Product name] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take [product name]**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how much [product name] you must take.

[Product name] must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be chewed, crushed or divided.

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 [product name] in adults is 30 mg (one tablet) once per day.

#### **If you are being treated for parathyroid cancer or primary hyperparathyroidism**

The usual starting dose for [product name] in adults is 30 mg (one tablet) twice per day.

#### **If you take more [product name] than you should**

If you take more [product name] 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 [product name]**

Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of [product name], you should take your next dose as normal.

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.

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 [product name] 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store [product name]

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 or blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine 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.

## **6. Contents of the pack and other information**

### **What [product name] contains**

- The active substance is cinacalcet. Each film-coated tablet contains cinacalcet hydrochloride equivalent to 30 mg, 60 mg or 90 mg of cinacalcet.
- The other ingredients are:  
*Tablet core:* maize starch pregelatinised, crospovidone, microcrystalline cellulose, silica, colloidal anhydrous, sodium stearyl fumarate  
*Film-coat:* hypromellose, lactose monohydrate, titanium dioxide (E 171), triacetin, macrogol

### **What [product name] looks like and contents of the pack**

#### [product name] 30 mg film-coated tablets:

White to off-white, oval shaped film-coated tablets debossed with '30' on one side, with a length of approximately 10.0 mm and a width of approximately 6.3 mm.

#### [product name] 60 mg film-coated tablets:

White to off-white, oval shaped film-coated tablets debossed with '60' on one side, with a length of approximately 12.5 mm and a width of approximately 7.9 mm.

#### [product name] 90 mg film-coated tablets:

White to off-white, oval shaped film-coated tablets debossed with '90' on one side, with a length of approximately 14.3 mm and a width of approximately 9.0 mm.

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

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### Marketing Authorisation Holder

Aristo Pharma GmbH  
Wallenroder Str. 8-10  
D-13435 Berlin  
Duitsland

### Manufacturer

Aristo Pharma GmbH  
Wallenroder Str. 8-10  
D-13435 Berlin  
Duitsland

**In het register ingeschreven onder:**

Cinacalcet Aristo 30 mg, filmomhulde tabletten	RVG 122974
Cinacalcet Aristo 60 mg, filmomhulde tabletten	RVG 122975
Cinacalcet Aristo 90 mg, filmomhulde tabletten	RVG 122976

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

Nederland:	Cinacalcet Aristo 30 mg/60 mg/90 mg, filmomhulde tabletten
Denemarken:	Cinacalcet Aristo 30 mg/60 mg/90 mg Filmtabletten
Duitsland:	Cinacalcet Aristo 30 mg/60 mg/90 mg Filmtabletten
Italië:	Cinacalcet Aristo
Noorwegen:	Cinacalcet Aristo
Oostenrijk:	Cinacalcet Aristo 30 mg/60 mg/90 mg Filmtabletten
Polen:	Cinacalcet Aristo
Portugal:	Cinacalcet Aristo
Spanje:	Cinacalcet Zentiva 30 mg/60 mg/90 mg comprimidos recubiertos con película EFG
Tsjechië:	Cinacalcet Aristo
Verenigd Koninkrijk:	Cinacalcet Aristo 30 mg/60 mg/90 mg film-coated tablets
Zweden:	Cinacalcet Aristo 30 mg/60 mg/90 mg filmdragerade tabletter

**This leaflet was last revised in March 2023.**