Package leaflet: Information for the patient

Orivantara 24 mg/26 mg filmomhulde tabletten
Orivantara 49 mg/51 mg filmomhulde tabletten
Orivantara 97 mg/103 mg filmomhulde tabletten

sacubitril/valsartan

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

What is in this leaflet

1. What Orivantara is and what it is used for

Orivantara is a heart medicine containing an angiotensin receptor neprilysin inhibitor. It delivers two active substances, sacubitril and valsartan.

Orivantara is used to treat a type of long-term heart failure in adults, children and adolescents (one year and older).

This type of heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

2. What you need to know before you take Orivantara

Do not take Orivantara
- if you are allergic to sacubitril, valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you are taking another type of medicine called an angiotensin converting enzyme (ACE) inhibitor (for example enalapril, lisinopril or ramipril), which is used to treat high blood pressure or heart failure. If you have been taking an ACE inhibitor, wait for 36 hours after taking the last dose before you start to take Orivantara (see “Other medicines and Orivantara ”).
- if you have ever had a reaction called angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs which can be life threatening if throat swelling blocks the airway) when taking an ACE inhibitor or an angiotensin receptor blocker (ARB) (such as valsartan, telmisartan or irbesartan).
- if you have a history of angioedema which is hereditary or for which the cause is unknown (idiopathic).

- if you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren (see "Other medicines and Orivantara").
- if you have severe liver disease.
- if you are more than 3 months pregnant (see "Pregnancy and breast-feeding").

If any of the above applies to you, do not take Orivantara and talk to your doctor.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before or when taking Orivantara:
- if you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see "Do not take Orivantara").
- if you have ever had angioedema (see "Do not take Orivantara" and section 4 "Possible side effects").
- if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Orivantara. Your doctor will decide on further treatment. Do not stop taking Orivantara on your own.
- if you have low blood pressure or are taking any other medicines that reduce your blood pressure (for example, a medicine that increases urine production (diuretic)) or are suffering from vomiting or diarrhoea, especially if you are aged 65 years or more, or if you have kidney disease and low blood pressure.
- if you have kidney disease.
- if you are suffering from dehydration.
- if your kidney artery has narrowed.
- if you have liver disease.
- if you experience hallucinations, paranoia or changes in sleeping pattern while taking Orivantara.
- if you have hyperkalaemia (high levels of potassium in the blood).
- if you suffer from heart failure classified as NYHA class IV (unable to carry on any physical activity without discomfort and may have symptoms even when resting).

If any of the above applies to you, tell your doctor, pharmacist or nurse before you take Orivantara.

Your doctor may check the amount of potassium and sodium in your blood at regular intervals during Orivantara treatment. In addition, your doctor may check your blood pressure at start of treatment and when the doses are increased.

Children and adolescents
Do not give this medicine to children aged below 1 year because it has not been studied in this age group. For children one year and older with a body weight below 40 kg, this medicine will be given as granules (instead of tablets).

Other medicines and Orivantara
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. It may be necessary to change the dose, to take other precautions, or even to stop taking one of the medicines. This is particularly important for the following medicines:
- ACE inhibitors. Do not take Orivantara with ACE inhibitors. If you have been taking an ACE inhibitor, wait 36 hours after taking the last dose of the ACE inhibitor before starting to take Orivantara (see "Do not take Orivantara"). If you stop taking Orivantara, wait 36 hours after taking your last dose of Orivantara before starting an ACE inhibitor.
- other medicines used to treat heart failure or lower blood pressure, such as angiotensin receptor blockers or aliskiren (see "Do not take Orivantara").
- some medicines known as statins that are used to lower high cholesterol levels (for example atorvastatin).
- sildenafil, tadalafil, vardenafil or avanafil, which are medicines used to treat erectile dysfunction or lung hypertension.
- medicines that increase the amount of potassium in the blood. These include potassium supplements, salt substitutes containing potassium, potassium-sparing medicines and heparin.

- painkillers of the type called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 (Cox-2) inhibitors. If you are taking one of these, your doctor may want to check your kidney function when starting or adjusting treatment (see "Warnings and precautions").
- lithium, a medicine used to treat some types of psychiatric illness.
- furosemide, a medicine belonging to the type known as diuretics, which are used to increase the amount of urine you produce.
- nitroglycerine, a medicine used to treat angina pectoris.
- some types of antibiotics (rifamycin group), ciclosporin (used to prevent rejection of transplanted organs) or antivirals such as ritonavir (used to treat HIV/AIDS).
- metformin, a medicine used to treat diabetes.

If any of the above applies to you, tell your doctor or pharmacist before you take Orivantara.

Pregnancy and breast-feeding
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.

Pregnancy
You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Orivantara.

This medicine is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

Breast-feeding
Orivantara is not recommended for mothers who are breast-feeding. Tell your doctor if you are breast-feeding or about to start breast-feeding.

Driving and using machines
Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Orivantara affects you. If you feel dizzy or very tired while taking this medicine, do not drive a vehicle, cycle or use any tools or machines.

Orivantara 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 Orivantara

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults
You will usually start by taking a 24 mg/26 mg or 49 mg/51 mg tablet twice a day (one tablet in the morning and one tablet in the evening). Your doctor will decide your exact starting dose based on which medicines you have been taking previously and your blood pressure. Your doctor will then adjust the dose every 2-4 weeks depending on how you respond to the treatment until the best dose for you is found.

The usual recommended target dose is 97 mg/103 mg twice a day (one tablet in the morning and one tablet in the evening).

Children and adolescents (one year and older)
Your (or your child's) doctor will decide the starting dose based on body weight and other factors including previously taken medicines. The doctor will adjust the dose every 2-4 weeks until the best dose is found.

Orivantara should be given twice a day (one tablet in the morning and one tablet in the evening).

Orivantara film-coated tablets are not meant to be used in children who weigh less than 40 kg. For these patients, sacbitril/valsartan granules are available.

Patients taking Orivantara can develop low blood pressure (dizziness, light-headedness), a high level of potassium in the blood (which would be detected when your doctor performed a blood test) or decreased kidney function. If this happens, your doctor may reduce the dose of any other medicine you are taking, temporarily reduce the Orivantara dose, or stop Orivantara treatment completely.

Swallow the tablets with a glass of water. You can take Orivantara with or without food. Splitting or crushing of the tablets is not recommended.

If you take more Orivantara than you should
If you have accidentally taken too many Orivantara tablets, or if someone else has taken your tablets, contact your doctor immediately. If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible and lie down.

If you forget to take Orivantara
It is advisable to take your medicine at the same time each day. However, if you forget to take a dose, you should simply take the next one at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Orivantara
Stopping your treatment with Orivantara may cause your condition to get worse. Do not stop taking your medicine unless your doctor tells you to.

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.
Some side effects may be serious.

- Stop taking sacubitril/valsartan and seek immediate medical attention if you notice any swelling of the face, lips, tongue and/or throat, which may cause difficulties in breathing or swallowing. These may be signs of angioedema (an uncommon side effect which may affect up to 1 in 100 people).

Other possible side effects:
If any of the side effects listed below becomes severe, tell your doctor or pharmacist.

Very common (may affect more than 1 in 10 people)

- low blood pressure, which can cause symptoms of dizziness and light-headedness (hypotension)
- high level of potassium in the blood, shown in a blood test (hyperkalaemia)
- decreased kidney function (renal impairment)

Common (may affect up to 1 in 10 people)

- cough
- dizziness
- diarrhoea

- low level of red blood cells, shown in a blood test (anaemia)
- tiredness (fatigue)
- (acute) inability of the kidney to work properly (renal failure)
- low level of potassium in the blood, shown in a blood test (hypokalaemia)
- headache
- fainting (syncope)
- weakness (asthenia)
- feeling sick (nausea)
- low blood pressure (dizziness, light-headedness) when switching from sitting or lying to standing position
- gastritis (stomach pain, nausea)
- spinning sensation (vertigo)
- low level of sugar in the blood, shown in a blood test (hypoglycaemia)

Uncommon (may affect up to 1 in 100 people)
- allergic reaction with rash and itching (hypersensitivity)
- dizziness when switching from sitting to standing position (dizziness postural)
- low level of sodium in the blood, shown in a blood test (hyponatraemia)

Rare (may affect up to 1 in 1 000 people)
- seeing, hearing or feeling things that are not there (hallucinations)
- changes in sleeping pattern (sleep disorder)

Very rare (may affect up to 1 in 10 000 people)
- paranoia
- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea

Not known (frequency cannot be estimated from the available data)
- sudden involuntary muscle twitching (myoclonus)

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 via
Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Orivantara

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.

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater. 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 Orivantara contains

The active substances are sacubitril and valsartan.

Orivantara 24 mg/26 mg tablets: Each film-coated tablet contains sacubitril sodium equivalent to 24.3 mg sacubitril and valsartan disodium equivalent to 25.7 mg valsartan.

Orivantara 49 mg/ 51 mg tablets: Each film-coated tablet contains sacubitril sodium equivalent to 48.6 mg sacubitril and valsartan disodium equivalent to 51.4 mg valsartan.

Orivantara 97 mg/ 103 mg tablets: Each film-coated tablet contains sacubitril sodium equivalent to 97.2 mg sacubitril and valsartan disodium equivalent to 102.8 mg valsartan.

The other ingredients in the tablet core are mannitol (E421), low-substituted hydroxypropylcellulose (E463), microcrystalline cellulose (102) (E460), crospovidone (type A) (E1202), silica colloidal hydrated (E551), magnesium stearate (E470b), talc (E553b).

The 24 mg/26 mg tablet coating contains hypromellose substitution type 2910 (50 mPas) (E464), titanium dioxide (E171), macrogol (3350) (E1521), iron oxide red (E172) and iron oxide black (E172).

The 49 mg/51 mg tablet coating contains hypromellose substitution type 2910 (50 mPas) (E464), titanium dioxide (E171), macrogol (3350) (E1521), iron oxide red (E172) and iron oxide yellow (E172).

The 97 mg/103 mg tablet coating contains hypromellose substitution type 2910 (3 mPas) (E464), titanium dioxide (E171), talc (E553b), macrogol (4000) (E1521), iron oxide red (E172) and iron oxide black (E172).

What Orivantara looks like and contents of the pack

Film-coated tablets (tablet).

Orivantara 24 mg/26 mg tablet: Violet white, ovaloid, biconvex film-coated tablets debossed with ‘C 50’ on upper side and plain on lower side with approximate dimensions of 7.8 x 4.0 mm.

Orivantara 49 mg/51 mg tablet: Pale yellow, ovaloid, biconvex film-coated tablets debossed with ‘C 100’ on upper side and plain on lower side with approximate dimensions of 12.0 x 5.0 mm.

Orivantara 97 mg/103 mg tablet: Light pink, ovaloid, biconvex film-coated tablets debossed with ‘C 200’ on upper side and plain on lower side with approximate dimensions of 15.1 x 6.0 mm.

Pack sizes: 28, 30, 56, 60, 196 film-coated tablets

OPA-Alu-PVC/ Alu blister in outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Alfred E. Tiefenbacher GmbH & Co. KG
Van-der-Smissen-Str. 1
22767 Hamburg
Duitsland

Manufacturer

Delorbis Pharmaceuticals Ltd.
17 Athinon Str., Ergates Industrial Area
2643 Ergates, Lefkosia
Cyprus

Pharmadox Healthcare Limited
Kw20a Kordin Industrial Park
Paola, PLA 3000
Malta

Marketing authorisation number
Orivantara 24 mg/26 mg filmomhulde tabletten: RVG 134486
Orivantara 49 mg/51 mg filmomhulde tabletten: RVG 134488
Orivantara 97 mg/103 mg filmomhulde tabletten: RVG 134490

This medicine is authorised in the Member States of the Europea Economic Area under the following names:

Nederland	Orivantara 24 mg/26 mg filmomhulde tabletten
	Orivantara 49 mg/51 mg filmomhulde tabletten
	Orivantara 97 mg/103 mg filmomhulde tabletten
Malta	Orivantara 24 mg/26 mg film-coated tablets
	Orivantara 49 mg/51 mg film-coated tablets
	Orivantara 97 mg/103 mg film-coated tablets

Deze Bijsluiter is voor het laatst goedgekeurd in oktober 2025.