Bijsluiter: informatie voor de patiënt

Sacubitril/Valsartan Synthon 24 mg/26 mg, filmomhulde tabletten
Sacubitril/Valsartan Synthon 49 mg/51 mg, filmomhulde tabletten
Sacubitril/Valsartan Synthon 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 [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] is a heart medicine containing an angiotensin receptor neprilysin inhibitor. It delivers two active substances, sacubitril and valsartan.

[Product name] 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 [Product name]

Do not take [Product name]
- 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 [Product name] (see “Other medicines and [Product name]”).
- 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 [Product name]”).
- 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 [Product name] and talk to your doctor.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before or when taking [Product name]:
- if you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see “Do not take [Product name]”).
- if you have ever had angioedema (see “Do not take [Product name]” and section 4 “Possible side effects”).
- if you experience abdominal pain, nausea, vomiting or diarrhoea after taking [Product name]. Your doctor will decide on further treatment. Do not stop taking [Product name] 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 [Product name].
- 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 [Product name].

Your doctor may check the amount of potassium and sodium in your blood at regular intervals during [Product name] 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 [Product name]
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 [Product name] 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 [Product name] (see “Do not take [Product name]”). If you stop taking [Product name], wait 36 hours after taking your last dose of [Product name] 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 [Product name]”).
- 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 [Product name].

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 [Product name].

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
[Product name] 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 [Product name] 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.

[Product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated 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.

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.

[Product name] should be given twice a day (one tablet in the morning and one tablet in the evening).

[Product name] film-coated tablets are not meant to be used in children who weigh less than 40 kg. For these patients, sacubitril/valsartan granules are available.

Patients taking [Product name] 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 [Product name] dose, or stop [Product name] treatment completely.

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

If you take more [Product name] than you should
If you have accidentally taken too many [Product name] 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 [Product name]
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 [Product name]
Stopping your treatment with [Product name] 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 [Product name] 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 het 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 [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 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 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 substances are sacubitril and valsartan.
  - Each 24 mg/26 mg film-coated tablet contains sacubitril sodium and valsartan disodium equivalent to 24.3 mg sacubitril and 25.7 mg valsartan.
  - Each 49 mg/51 mg film-coated tablet contains sacubitril sodium and valsartan disodium equivalent to 48.6 mg sacubitril and 51.4 mg valsartan.
  - Each 97 mg/103 mg film-coated tablet contains sacubitril sodium and valsartan disodium equivalent to 97.2 mg sacubitril and 102.8 mg valsartan.
- The other ingredients in the tablet core are cellulose, microcrystalline; hydroxypropylcellulose, low-substituted; crospovidone type A and B; talc; silica, colloidal anhydrous and magnesium stearate.
- The 24 mg/26 mg tablet coating contains poly(vinyl alcohol) - partially hydrolysed; titanium dioxide; macrogol and talc.

- The 49 mg/51 mg tablet coating contains poly(vinyl alcohol) - partially hydrolysed; titanium dioxide; macrogol; talc; iron oxide red (E172) and iron oxide yellow (E172).
- The 97 mg/103 mg tablet coating contains poly(vinyl alcohol) - partially hydrolysed; titanium dioxide; macrogol; talc; iron oxide red (E172) and iron oxide yellow (E172).

What [Product name] looks like and contents of the pack
[Product name] 24 mg/26 mg film-coated tablets (tablets) are white, biconvex, oval film-coated tablets debossed with “S7V” on one side and “L1” on the other side. Approximate tablet dimensions 13 mm x 5 mm.

[Product name] 49 mg/51 mg film-coated tablets (tablets) are pink, biconvex, oval film-coated tablets debossed with “S7V” on one side and “M2” on the other side. Approximate tablet dimensions: 12 mm x 5 mm.

[Product name] 97 mg/103 mg film-coated tablets (tablets) are pink, biconvex, oval film-coated tablets debossed with “S7V” on one side and “H3” on the other side. Approximate tablet dimensions: 16 mm x 6 mm.

[Product name] is available in blister packs containing 28, 30, 56 or 60 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Synthon B.V.
Microweg 22
6545 CM Nijmegen
Nederland

Fabrikanten:
Synthon Hispania S.L.
Calle De Castello 1
Sant Boi De Llobregat
08830 Barcelona
Spanje

Synthon B.V.
Microweg 22
6545 CM Nijmegen
Nederland

In het register inschreven onder:

Sacubitril/Valsartan Synthon 24 mg/26 mg, filmomhulde tabletten	RVG 137199
Sacubitril/Valsartan Synthon 49 mg/51 mg, filmomhulde tabletten	RVG 137200
Sacubitril/Valsartan Synthon 97 mg/103 mg, filmomhulde tabletten	RVG 137201

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2026.