

**1.5 Product Information****1.5.3 Patient information leaflet****SACUVAN 24/ 26 (Sacubitril and Valsartan Tablets 24 mg/ 26 mg)**

Read all of this leaflet carefully before you start having 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 Sacubitril and Valsartan is and what it is used for
2. What you need to know before you take Sacubitril and Valsartan
3. How to take Sacubitril and Valsartan
4. Possible side effects
5. How to store Sacubitril and Valsartan
6. Contents of the pack and other information

1. What Sacubitril and Valsartan is and what it is used for

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

Sacubitril and Valsartan is used to treat a type of long-term heart failure in adults.

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 Sacubitril and Valsartan**Do not take Sacubitril and Valsartan:**

- 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). ACE inhibitors are

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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 Sacubitril and Valsartan (see “Other medicines and Sacubitril and Valsartan”).

- if you or a member of your family have ever had a reaction called angioedema (swelling of the face, lips, tongue and/or throat, difficulties in breathing) when taking an ACE inhibitor or an angiotensin receptor blocker (ARB) (such as valsartan, telmisartan or irbesartan).
- 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 Sacubitril and Valsartan”).
- if you have severe liver disease.
- if you are more than 3 months pregnant (it is also better to avoid this medicine in early pregnancy, see “Pregnancy and breast-feeding”). If any of the above applies to you, do not take Sacubitril and Valsartan and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or when taking Sacubitril and Valsartan:

- if you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see “Do not take Sacubitril and Valsartan”).
- if you have ever had angioedema (see “Do not take Entresto” and section 4 “Possible side effects”).
- if you have low blood pressure or are taking any other medicines that reduce your blood pressure (for example, a 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 severe 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.

Your doctor may check the amount of potassium in your blood at regular intervals during Sacubitril and Valsartan treatment.



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

Children and adolescents

Do not give this medicine to children (aged below 18 years) because it has not been studied in this age group.

Other medicines and Sacubitril and Valsartan

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 Sacubitril and Valsartan 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 Entresto (see “Do not take Sacubitril and Valsartan”). If you stop taking Sacubitril and Valsartan, wait 36 hours after taking your last dose of Sacubitril and Valsartan 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 Sacubitril and Valsartan”).
- some medicines known as statins that are used to lower high cholesterol levels (for example atorvastatin).
- sildenafil, a medicine 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).

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- metformin, a medicine used to treat diabetes

If any of the above applies to you, tell your doctor or pharmacist before you take Sacubitril and Valsartan

Pregnancy and breastfeedingPregnancy

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 Sacubitril and Valsartan.

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

Sacubitril and Valsartan is not recommended for mothers who are breast-feeding. Tell your doctor if you are breastfeeding 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 Sacubitril and Valsartan 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.

3. How to take Sacubitril and Valsartan

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

You will usually start by taking 24 mg/26 mg or 49 mg/51 mg 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. Your doctor will then adjust the dose 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).

Patients taking Sacubitril and Valsartan 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

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reduce the dose of any other medicine you are taking, temporarily reduce your Sacubitril and Valsartan dose, or stop your Sacubitril and Valsartan treatment completely.

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

If you take more Sacubitril and Valsartan than you should

If you have accidentally taken too many Sacubitril and Valsartan 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 Sacubitril and Valsartan

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 tablet.

If you stop taking Sacubitril and Valsartan

Stopping your treatment with Sacubitril and Valsartan 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 and 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 (dizziness, light-headedness)
- high level of potassium in the blood (shown in a blood test)
- decreased renal function (renal impairment)

Common (may affect up to 1 in 10 people)

- cough
- dizziness

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- diarrhoea
- low level of red blood cells (shown in a blood test)
- tiredness
- (acute) renal failure (severe kidney disorder)
- low level of potassium in the blood (shown in a blood test)
- headache
- fainting
- weakness
- feeling sick (nausea)
- low blood pressure (dizziness, light-headedness) when switching from sitting or lying to standing position
- gastritis (stomach pain, nausea)
- spinning sensation
- low level of sugar in the blood (shown in a blood test)

Uncommon (may affect up to 1 in 100 people)

- allergic reaction with rash and itching
- dizziness when switching from sitting to standing position

Rare (may affect up to 1 in 1,000 people)

- hallucinations
- changes in sleeping pattern

Very rare (may affect up to 1 in 10,000 people)

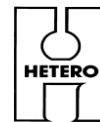
- paranoia

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sacubitril and Valsartan

Keep this medicine out of the sight and reach of children.

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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 Sacubitril and Valsartan contains

- The active substances are sacubitril and valsartan.
 - o Each film-coated tablet contains Sacubitril 24 mg and Valsartan 26 mg
 - o Each film-coated tablet contains Sacubitril 49 mg and Valsartan 51 mg
 - o Each film-coated tablet contains Sacubitril 97 mg and Valsartan 103 mg

Tablet core

Micro crystalline cellulose, Low substituted Hydroxypropyl cellulose (LH-11), Povidone, Isopropyl alcohol, Crospovidone, Silicon dioxide, Magnesium Stearate, Colloidal Silicon dioxide.

Tablet Coating:*Sacubitril and valsartan Tablets 24 mg/26 mg*

Hypromellose, Di-Acetylated Monoglycerides, Titanium Dioxide, Methylene chloride

Sacubitril and valsartan Tablets 49 mg/51 mg

Hypromellose, Di-Acetylated Monoglycerides, Titanium Dioxide, FD&C Blue #2/Indigo Carmine AL 3% - 5%, FD&C Blue #2/Indigo Carmine Aluminum Lake

Sacubitril and valsartan Tablets 97mg/103 mg

Hypromellose, Di-Acetylated Monoglycerides, Iron Oxide Red, Titanium Dioxide

**Module 1-Administrative and Regional Information****What Sacubitril and Valsartan looks like and contents of the pack**

Sacubitril and Valsartan 24 mg/26 mg film-coated tablets are white colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S24' on the other side.

Sacubitril and Valsartan 49 mg/51 mg film-coated tablets are blue colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S25' on the other side.

Sacubitril and Valsartan 97 mg/103 mg film-coated tablets are brown colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S26' on the other side.

The tablets are supplied in packs containing 3 x 10's Blister pack

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