PACKAGE LEAFLET

Package leaflet: Information for the patient

Sacubitril/Valsartan Teva 24 mg/26 mg film-coated tablets
Sacubitril/Valsartan Teva 49 mg/51 mg film-coated tablets
Sacubitril/Valsartan Teva 97 mg/103 mg film-coated tablets

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 Sacubitril/Valsartan Teva is and what it is used for
2. What you need to know before you take Sacubitril/Valsartan Teva
3. How to take Sacubitril/Valsartan Teva
4. Possible side effects
5. How to store Sacubitril/Valsartan Teva
6. Contents of the pack and other information

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

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

Sacubitril/Valsartan Teva 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/Valsartan Teva

Do not take Sacubitril/Valsartan Teva
- 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 this medicine (see "Other medicines and Sacubitril/Valsartan Teva").
- 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 Sacubitril/Valsartan Teva").
- 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 Sacubitril/Valsartan Teva and talk to your doctor.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before or when taking Sacubitril/Valsartan Teva.

- if you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see "Do not take Sacubitril/Valsartan Teva").
- if you have ever had angioedema (see "Do not take Sacubitril/Valsartan Teva" and section 4 "Possible side effects").
- if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Sacubitril/Valsartan Teva. Your doctor will decide on further treatment. Do not stop taking this medicine 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 Sacubitril/Valsartan Teva.
- 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 Sacubitril/Valsartan Teva.

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

Children and adolescents
For children and adolescents other medicinal products containing sacubitril and valsartan should be used instead of Sacubitril/Valsartan Teva.

Other medicines and Sacubitril/Valsartan Teva
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/Valsartan Teva 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 this medicine (see "Do not take Sacubitril/Valsartan Teva"). If you stop taking this medicine, wait 36 hours after taking your last dose of Sacubitril/Valsartan Teva 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/Valsartan Teva").
- 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 Sacubitril/Valsartan Teva.

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 Sacubitril/Valsartan Teva.

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/Valsartan Teva 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 Sacubitril/Valsartan Teva 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.

Sacubitril/Valsartan Teva 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 Sacubitril/Valsartan Teva

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).

Sacubitril/Valsartan Teva should be given twice a day (one tablet in the morning and one tablet in the evening).

Sacubitril/Valsartan Teva film-coated tablets are not meant to be used in children.
For these patients, other medicines containing sacubitril and valsartan should be used instead of Sacubitril/Valsartan Teva.

Patients taking Sacubitril/Valsartan Teva 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 Sacubitril/Valsartan Teva dose, or stop Sacubitril/Valsartan Teva treatment completely.

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

If you take more Sacubitril/Valsartan Teva than you should
If you have accidentally taken too many Sacubitril/Valsartan Teva 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/Valsartan Teva
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 Sacubitril/Valsartan Teva
Stopping your treatment with Sacubitril/Valsartan Teva 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 Teva 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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sacubitril/Valsartan Teva

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 Sacubitril/Valsartan Teva contains

- The active substances are sacubitril and valsartan.
  - Each 24 mg/26 mg film-coated tablet contains sacubitril sodium equivalent to 24.3 mg sacubitril and valsartan disodium equivalent to 25.7 mg valsartan.
  - Each 49 mg/51 mg film-coated tablet contains sacubitril sodium equivalent to 48.6 mg sacubitril and valsartan disodium equivalent to 51.4 mg valsartan.
  - Each 97 mg/103 mg 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 cellulose, microcrystalline, talc, low-substituted hydroxypropylcellulose, crospovidone, magnesium stearate (see end of section 2 under 'Sacubitril/Valsartan Teva contains sodium').
- The 24 mg/26 mg and the 97 mg/103 mg tablet coating contains hypromellose, titanium dioxide (E171), talc, macrogol 4 000, iron oxide red (E172) and iron oxide black (E172).
- The 49 mg/51 mg tablet coating contains hypromellose, titanium dioxide (E171), talc, macrogol 4 000, iron oxide yellow (E172) and iron oxide red (E172).

What Sacubitril/Valsartan Teva looks like and contents of the pack

Sacubitril/Valsartan Teva 24 mg/26 mg film-coated tablets are violet white round film-coated tablets, unscored, debossed with "L" on one side, plain on the other side. Approximate tablet diameter 6.0 mm.

Sacubitril/Valsartan Teva 49 mg/51 mg film-coated tablets are pale yellow ovaloid biconvex film-coated tablets, unscored, with bevelled edges, debossed with "I" on one side and plain on the other side. Approximate tablet dimensions 13.1 mm x 5.2 mm.

Sacubitril/Valsartan Teva 97 mg/103 mg film-coated tablets are light pink, ovaloid biconvex film-coated tablets, unscored, with beveled edges debossed with "H" on one side, plain on the other side. Approximate tablets dimensions 15.1 mm x 6.0 mm.

PVC/PCTFE (Aclar)//Alu blister and perforated unit dose blisters packed into carton boxes.

For Sacubitril/Valsartan Teva 24 mg/26 mg film-coated tablets
Pack sizes of 28, 30, 56, 20x1, 28x1, 30x1, 56x1, 196x1 film-coated tablets.

For Sacubitril/Valsartan Teva 49 mg/51 mg film-coated tablets
Pack sizes of 28, 56, 60, 168, 20x1, 28x1, 56x1, 60x1, 196x1 film-coated tablets.

For Sacubitril/Valsartan Teva 97 mg/103 mg film-coated tablets
Pack sizes of 28, 56, 60, 168, 20x1, 56x1, 60x1, 196x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
TEVA GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

Manufacturer
ELPEN Pharmaceutical Co. Inc.
Marathonos Avenue 95,
Pikermi Attiki, 19009,
Greece

ELPEN Pharmaceutical Co. Inc.

Zapani, Block 1048,
Keratea, 19001,
Greece

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

Austria	Sacubitril/Valsartan ratiopharm 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg Filmtabletten
Belgium	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg Teva filmomhulde tabletten, comprimés pelliculés, Filmtabletten
Czech Republic	Sakubitril/Valsartan Teva
Germany	Sacubitril/Valsartan-ratiopharm 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg Filmtabletten
Denmark	Sacubitril/Valsartan Teva
Estonia	Sacubitril/Valsartan Teva
Finland	Sacubitril/Valsartan ratiopharm 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg tabletti, kalvopäällysteinen
France	SACUBITRIL/VALSARTAN TEVA 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg comprimé pelliculé
Hungary	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg filmtabletta
Iceland	Sacubitril/Valsartan Teva
Ireland	Sacubitril/Valsartan Teva Film-coated Tablets
Italy	SACUBITRIL e VALSARTAN TEVA
Latvia	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg apvalkotās tabletes
Lithuania	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg plėvele dengtos tabletės
Luxembourg	Sacubitril/Valsartan-ratiopharm 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg Filmtabletten
Netherlands	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg filmomhulde tabletten
Norway	Sacubitril/Valsartan Teva
Poland	Sacubitril + Valsartan Teva
Romania	Sacubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg comprimate filmate
Sweden	Sacubitril/Valsartan Teva
Slovakia	Sakubitril/Valsartan Teva 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg filmom obalené tablety
Spain	Sacubitrilo/Valsartán Teva 24 mg/26 mg comprimidos recubiertos con película EFG

This leaflet was last revised in June 2025.