Pharmacor Sacubitril/Valsartan Film-coated Tablets 24/26 mg, 49/51 mg, 97/103 mg

sacubitril and valsartan

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Pharmacor Sacubitril/Valsartan?

Pharmacor Sacubitril/Valsartan film-coated tablets contains the active ingredient sacubitril and valsartan. Pharmacor Sacubitril/Valsartan is used to treat heart failure. For more information, see Section 1. Why am I using Pharmacor Sacubitril/Valsartan? in the full CMI.

2. What should I know before I use Pharmacor Sacubitril/Valsartan?

Do not use if you have ever had an allergic reaction to Pharmacor Sacubitril/Valsartan or any of the ingredients listed at the end of the CMI. Do not take Pharmacor Sacubitril/Valsartan if you are pregnant, taking medicines similar to Pharmacor Sacubitril/Valsartan or have severe liver problems.

Talk to your doctor if you have any other medical conditions, take any other medicines, plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Pharmacor Sacubitril/Valsartan? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pharmacor Sacubitril/Valsartan and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI for information.

4. How do I use Pharmacor Sacubitril/Valsartan?

- Take one tablet in the morning and one tablet in the evening (your doctor will tell you what strength) either with food or without food.

More instructions can be found in Section 4. How do I use Pharmacor Sacubitril/Valsartan? in the full CMI.

5. What should I know while using Pharmacor Sacubitril/Valsartan?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Pharmacor Sacubitril/Valsartan. • Avoid becoming pregnant while using Pharmacor Sacubitril/Valsartan.
Things you should not do	• Do not stop using this medicine suddenly. • Do not take another medicine for high blood pressure or heart failure from a class known as angiotensin converting enzyme inhibitor.
Driving or using machines	• Pharmacor Sacubitril/Valsartan may cause dizziness or tiredness in some people.
Drinking alcohol	• There are no known interactions between Pharmacor Sacubitril/Valsartan and alcohol.
Looking after your medicine	• Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using Pharmacor Sacubitril/Valsartan? in the full CMI.

6. Are there any side effects?

Common side effects include: dizziness, fainting, light-headedness, cough, headache, diarrhoea, feeling sick, stomach pain, tiredness, weakness. Serious side effects include: swelling of the face, lips, tongue and/or throat and difficulty breathing and/or swallowing.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Pharmacor Sacubitril/Valsartan

Active ingredient(s): *sacubitril and valsartan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pharmacor Sacubitril/Valsartan. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Pharmacor Sacubitril/Valsartan.

Where to find information in this leaflet:

1. Why am I using Pharmacor Sacubitril/Valsartan?
2. What should I know before I use Pharmacor Sacubitril/Valsartan?
3. What if I am taking other medicines?
4. How do I use Pharmacor Sacubitril/Valsartan?
5. What should I know while using Pharmacor Sacubitril/Valsartan?
6. Are there any side effects?
7. Product details

1 . Why am I using Pharmacor Sacubitril/Valsartan?

Pharmacor Sacubitril/Valsartan is used to treat heart failure in adults. Pharmacor Sacubitril/Valsartan has been shown to lower the risk of cardiovascular related deaths and heart failure related hospitalisation.

Pharmacor Sacubitril/Valsartan contains the active ingredients sacubitril and valsartan. It is an angiotensin receptor neprilysin inhibitor (ARNI), which contains two active ingredients: sacubitril (a neprilysin inhibitor), and valsartan (an angiotensin receptor blocker or ARB). Pharmacor Sacubitril/Valsartan works by blocking the changes caused by the enzyme neprilysin, and angiotensin-II. As a result, blood vessels relax and less water is kept by the body which is useful to treat heart failure.

2. What should I know before I use Pharmacor Sacubitril/Valsartan?

Warnings

Do not use Pharmacor Sacubitril/Valsartan if:

- you are allergic to sacubitril or valsartan, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are taking another medicine for high blood pressure or heart failure from a class known as angiotensin converting enzyme (ACE) inhibitor
- you have taken another medicine containing an ACE inhibitor within the last 36 hours
- you or someone in your family, have had a reaction before that causes swelling of the face, lips, tongue and/or throat, with or without difficulties in breathing while taking an ACE inhibitor or an ARB in the past.
- you are taking a medicine called aliskiren and have Type 2 diabetes (high level of sugar in the blood)
- you have severe liver disease.

Check with your doctor if you:

- are already taking any medicine that is an ACE inhibitor or ARB
- have low blood pressure
- are taking other medicines that lower your blood pressure
- have ever experienced swelling of the face, lips, tongue and/or throat, with or without difficulties in breathing
- have kidney problems
- have liver problems
- are taking any medicines that increase the amount of potassium in your blood, or potassium supplements, salt substitutes that contain potassium, potassium-sparing medicines, or heparin
- have any other medical condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or plan to become pregnant. If you become pregnant or think you are pregnant, tell your doctor right away.

Check with your doctor if you want to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Contraception

To avoid becoming pregnant, you should use contraception while using Pharmacor Sacubitril/Valsartan and for 1 week after you stop using it.

Use in children

It is not known whether Pharmacor Sacubitril/Valsartan is safe and effective in patients below 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines not to be taken with Pharmacor Sacubitril/Valsartan include:

- any medicine that is an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)

Ask your doctor or pharmacist if you are unsure if you are being treated with these other medicines. ACE inhibitors and ARBs are sold under many different brand names in Australia and New Zealand.

Some medicines may interfere with Pharmacor Sacubitril/Valsartan. These include:

- statins, a medicine used to lower cholesterol levels e.g. atorvastatin
- sildenafil, a medicine used to treat erectile dysfunction and certain types of high blood pressure
- medicines that increase the amount of potassium in the blood, including potassium sparing diuretics, a medicine used to reduce excess fluid in your body, e.g. amiloride
- medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAID) or selective cyclo-oxygenase-2 inhibitors (COX-2) inhibitors, e.g. ibuprofen
- lithium, a medicine used to treat some types of depression
- frusemide, a medicine used to reduce excess fluid in the body
- metformin, a medicine used to control blood glucose for diabetes
- some antibiotics, e.g. rifampicin, a medicine used to treat certain infections
- ciclosporin, a medicine to treat certain problems with the immune system, or to help prevent organ transplant rejection
- ritonavir, a medicine used to treat HIV/AIDS infection.

Tell your doctor if you take potassium supplements or salt substitutes that contain potassium.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pharmacor Sacubitril/Valsartan.

4. How do I use Pharmacor Sacubitril/Valsartan?

How much to take

- Your doctor will decide how many tablets you should take
- The usual starting dose is one 49 mg/51 mg (pale yellow) tablet taken twice a day
- Some patients will start at a lower dose
- Your doctor will adjust the dose based on how you respond to treatment after 2 to 4 weeks until the best dose for you is found
- Follow the instructions provided and use Pharmacor Sacubitril/Valsartan until your doctor tells you to stop.

When to take Pharmacor Sacubitril/Valsartan

- Take one tablet in the morning and one tablet in the evening.

How to take Pharmacor Sacubitril/Valsartan

- Swallow Pharmacor Sacubitril/Valsartan tablets whole.
- Take Pharmacor Sacubitril/Valsartan either with food or without food.

If you forget to use Pharmacor Sacubitril/Valsartan

Pharmacor Sacubitril/Valsartan should be taken regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much Pharmacor Sacubitril/Valsartan

If you think that you have taken too much Pharmacor Sacubitril/Valsartan, you may need urgent medical attention. You may feel dizzy or lightheaded if you take too much Pharmacor Sacubitril/Valsartan.

You should immediately:

- phone the Poisons Information Centre by calling (13 11 26) in Australia or (0800 764 766) in New Zealand, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Pharmacor Sacubitril/Valsartan?

Things you should do

Call your doctor straight away if you:

- show signs of swelling of the face, lips, tongue and/or throat, and difficulty in breathing

- become pregnant while taking Pharmacor Sacubitril/Valsartan.

Remind any doctor, dentist or pharmacist you visit that you are using Pharmacor sacubitril/Valsartan.

Keep all appointments with your doctor so your progress can be checked regularly. Your doctor may want to check your kidney function, blood cell counts, blood pressure, sugar and potassium levels.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not take ACE inhibitors at the same time as this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pharmacor Sacubitril/Valsartan affects you.

Pharmacor Sacubitril/Valsartan may cause dizziness or tiredness in some people.

Drinking alcohol

Be careful drinking alcohol until you know how this medicine affects you.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut side effects: • Constipation • Diarrhoea • Feeling sick, vomiting • Stomach pain **Infections:** • Flu-like symptoms such as fever, sore throat, cough, chills • Runny nose, blocked nose • Burning sensation when urinating • Urinating more frequently **General side effects:** • Dizziness • Light-headed, feeling faint • dizziness when moving from sitting or lying down to a standing position • Tiredness • Headache • Weakness • Trouble sleeping • Back pain, joint pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, pharmacist, or health care provider**

Serious side effects

Serious side effects	What to do
• Chest pain, feeling of tightness or pressure in the chest • Fast heart beat • Shortness of breath • Swelling of the feet, ankles or hands • Wheezing, trouble breathing, persistent cough	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• **Severe allergic reaction signs:** • Swollen face, tongue, lips or throat • Difficulty in swallowing • Difficulty in breathing • Rash, itching.	**Stop taking Pharmacor Sacubitril/Valsartan and call your doctor straight away, or go to the Emergency Department at your nearest hospital if you notice any signs of an allergic reaction.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects (for example problems with kidneys, low red blood cells, low sugar levels in the blood, high or low levels of potassium in the blood, low blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at www.medsafe.govt.nz/safety/report-a-problem.asp.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Pharmacor Sacubitril/Valsartan contains

Active ingredients (main ingredients)	Sacubitril and Valsartan
Other ingredients (inactive ingredients)	• microcrystalline cellulose • hydroxyl propyl cellulose , • Sodium Starch Glycolate (Type A) • magnesium stearate • colloidal silicon dioxide • talc The film-coating on the tablets contains: • Opadry 03F580070 White [Hypromellose,Titanium dioxide, Macrogol, Talc, Ferrosoferric oxide/Black iron oxide, Iron oxide red and Iron oxide yellow] (only for the 24 mg/26 mg tablets) • Opadry 03F520320 Yellow [Hypromellose, Titanium dioxide, Macrogol, Talc and Iron oxide yellow] (only for the 49 mg/ 51mg tablets) •Opadry 03F540210Pink [Hypromellose, Titanium dioxide, Macrogol, Talc, Ferrosoferric oxide/Black iron oxide, Iron oxide red and Iron oxide yellow](only for the 97 mg/103mg tablets)

Potential Allergen: None Pharmacor Sacubitril / Valsartan does not contain lactose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Pharmacor Sacubitril/Valsartan looks like

24 mg/26 mg: Off white to light pink, ovaloid biconvex, film-coated tablets with bevelled edge unscored, debossed with 'SV5' on one side and plain on the other side.

49 mg/51 mg: Pale yellow to yellow, ovaloid biconvex, film-coated tablets with bevelled edge unscored, debossed with 'SV1' on one side and plain on the other side.

97 mg/103 mg: Light pink to pink, ovaloid biconvex, film-coated tablets with bevelled edge unscored, debossed with 'SV2' on one side and plain on the other side.

Who distributes Pharmacor Sacubitril / Valsartan

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AUST R 355480- PHARMACOR SACUBITRIL / VALSARTAN sacubitril/valsartan (combined as sodium salts)24/26 mg film- coated tablet blister pack

AUST R 355476- PHARMACOR SACUBITRIL/VALSARTANsacubitril/valsartan (combined as sodium salts)49/51 mg film- coated tablet blister pack

AUST R 355481- PHARMACOR SACUBITRIL/VALSARTAN sacubitril/valsartan (combined as sodium salts)97/103 mg film- coated tablet blister pack

AUST R 355479-PHARMACOR SACUBITRIL/VALSARTAN sacubitril/valsartan (combined as sodium salts)24/26mg film-coated tablet bottle pack

AUST R 355473-PHARMACOR SACUBITRIL/VALSARTAN sacubitril/valsartan (combined as sodium salts)49/51mg film-coated tablet bottle pack

AUST R 355474-PHARMACOR SACUBITRIL/VALSARTAN sacubitril/valsartan (combined as sodium salts)97/103mg film-coated tablet bottle pack