SACUBASSEL (Sacubitril/Valsartan film-coated tablets)

sacubitril/valsartan (50mg, 100mg, 200mg)

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What Sacubassel is used for

Sacubassel is a medicine known as an angiotensin receptor neprilysin inhibitor. It dissociates into two active substances, sacubitril and valsartan. They both help to treat heart failure and control high blood pressure.

Sacubassel 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.

Sacubassel is also used to treat high blood pressure in adults. High blood pressure increases the workload of the heart and arteries. If it continues for a long time, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

How Sacubassel works

Sacubassel works by blocking the effects of neprilysin via sacubitril and angiotensin-II receptor via valsartan. As a result, blood vessels relax and less water is retained by the body which is beneficial to treat heart failure and high blood pressure.

If you have any questions about how Sacubassel works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

Before you take Sacubassel

When you must not use it:

Do not take Sacubassel

- if you are allergic to sacubitril, valsartan or any of the other ingredients of this medicine (listed in "Product description"). If you think you may be allergic to any component of this medicine, talk to your doctor before taking Sacubassel.
- if you are taking another type of medicine called an angiotensin converting enzyme (ACE) inhibitor (for example enalapril, lisinopril or ramipril). ACE inhibitors are 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 Sacubassel (see "Taking other medicines").
- 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 "Taking other medicines").
- 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 Sacubassel and talk to your doctor.

Before you start to use it

Talk to your doctor, pharmacist or nurse before or when taking Sacubassel:

- if you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see "Do not take Sacubassel").
- if you have ever had angioedema (see "Do not take Sacubassel" and "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 Sacubassel treatment.

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

Children and adolescents

This medicine is not for use in children (aged below 18 years). This is because it has not been studied in this age group.

Pregnancy and breast-feeding

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

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soon as you know you are pregnant, and will advise you to take another medicine instead of Sacubassel. 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
Sacubassel 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 Sacubassel 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.

Taking other medicines
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 Sacubassel 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 Sacubassel (see "Do not take Sacubassel"). If you stop taking Sacubassel, wait 36 hours after taking your last dose of Sacubassel 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 Sacubassel").
- 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 "Before you start to use it").
- 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.
- Nitroglycerin, a medicine used to treat angina.
- 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 Sacubassel.

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

How much to use
To treat heart failure, the usual recommended target dose is 200 mg twice a day (one tablet in the morning and one tablet in the evening).

You will usually start by taking 50mg or 100mg twice a day (one tablet in the morning and one tablet in the evening).

To treat high blood pressure, the usual recommended target dose is 200 mg once a day. In some cases, your doctor may prescribe a higher dose (e.g. 400 mg once a day) or an additional medicine (e.g. a diuretic). ACE inhibitors and ARBs should not be used.

For both indications, 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.

If you were taking ACE inhibitors previously, do not take Sacubassel until 36 hours after your last dose of the ACE inhibitor. If you are currently taking an ARB, stop taking it.

Patients taking Sacubassel 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 your Sacubassel dose, or stop your Sacubassel treatment completely.

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

When to use Sacubassel
Take one tablet in the morning and one tablet in the evening. Taking Sacubassel at the same time each

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day will help you to remember when to take your medicine.

How long to use Sacubassel
Continue taking Sacubassel every

day for as long as your doctor tells you. If you have questions about how long to take Sacubassel, talk to your doctor or your pharmacist or healthcare provider.

If you forget to use Sacubassel
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 use too much (overdose)
If you have accidentally taken too many Sacubassel 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using Sacubassel
Things you must do
Take your medicine exactly as your doctor has told you.

Things you must not do
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.

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

Things to be careful of
Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be serious.
- Stop taking Sacubassel 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
- 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 1000 people)
- hallucinations
- changes in sleeping pattern

Very rare (may affect up to 1 in 10000 people)
- paranoia

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF)].

Storage and disposal of Sacubassel
- *Storage*
- Store below 30°C. Store in the original package in order to protect from moisture.
- 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.

- *Disposal*

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.

Product Description
What it looks like
Sacubassel is supplied as film-coated tablets and is available in 3 different strengths 50mg, 100mg, or 200mg.
- 50mg tablets are Off white to Light Pink, oval, biconvex

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film coated tablets, debossed with '5' on one side and plain on other side.

- 100mg tablets are Light Yellow color, oval, biconvex film coated tablets, debossed with '|' on one side and plain on other side
- 200mg tablets are Light pink to Pink, oval, biconvex film coated tablets, debossed with '2' on one side and plain on other side.

Ingredients:

- *Active Ingredients*

The active substance of Sacubassel is sacubitril/valsartan.

• Each 50mg film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex).

• Each 100mg film-coated tablet contains 48.6 mg sacubitril and 51.4 mg valsartan (as sacubitril valsartan sodium salt complex).

• Each 200mg film-coated tablet contains 97.2 mg sacubitril and 102.8 mg valsartan (as sacubitril valsartan sodium salt complex).

- *Inactive Ingredients*

The other inactive ingredients of Sacubassel are Microcrystalline Cellulose (PH 102), L-HPC(LH-11), Crospovidone (kollidon CL), Talc, Colloidal Silicon Dioxide, Magnesium Stearate

Film- coating excipients:
For 50mg film coating:
Hypromellose, Titanium dioxide, Macrogol, Talc, Iron oxide red and Black iron oxide

For 100mg film coating:
Hypromellose, Titanium dioxide, Macrogol, Talc, Iron oxide red, Iron oxide yellow and Black iron oxide

For 200 mg film coating:
Hypromellose, Titanium dioxide, Macrogol, Talc, Iron oxide red and Black iron oxide

MAL Number:
50mg - MAL26046053AZ
100mg - MAL26046056AZ
200mg - MAL26046057AZ

Manufacturer
Dr. Reddy's Laboratories Ltd.,
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Product Registration Holder
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