

PATIENT INFORMATION LEAFLET FOR
SACUBITRIL VALSARTAN 24/26 mg CIPLA
SACUBITRIL VALSARTAN 49/51 mg CIPLA
SACUBITRIL VALSARTAN 97/103 mg CIPLA

SCHEDULING STATUS: **S3**

SACUBITRIL VALSARTAN 24/26 mg CIPLA film-coated tablets
SACUBITRIL VALSARTAN 49/51 mg CIPLA film-coated tablets
SACUBITRIL VALSARTAN 97/103 mg CIPLA film-coated tablets

Sacubitril/valsartan

Sugar free.

Read all of this leaflet carefully before you start taking SACUBITRIL VALSARTAN CIPLA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- SACUBITRIL VALSARTAN CIPLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What SACUBITRIL VALSARTAN CIPLA is and what is used for
2. What you need to know before you take SACUBITRIL VALSARTAN CIPLA

3. How to take SACUBITRIL VALSARTAN CIPLA
4. Possible side effects
5. How to store SACUBITRIL VALSARTAN CIPLA
6. Contents of the pack and other information.

1. What SACUBITRIL VALSARTAN CIPLA is and what is used for

SACUBITRIL VALSARTAN CIPLA contains two active ingredients called sacubitril and valsartan. SACUBITRIL VALSARTAN CIPLA is used in adults as a second line treatment to replace ACE (angiotensin-converting enzyme) inhibitors or ARB's (angiotensin receptor blockers) to treat heart failure. SACUBITRIL VALSARTAN CIPLA is used together with other medicines that are used to treat heart failure.

2. What you need to know before you take SACUBITRIL VALSARTAN CIPLA

Do not take SACUBITRIL VALSARTAN CIPLA:

- If you are hypersensitive (allergic) to sacubitril or valsartan or any of the other ingredients of SACUBITRIL VALSARTAN CIPLA (listed in **section 6**).
- If you are currently taking any other medicines called ACE (angiotensin converting enzyme) inhibitors (for example enalapril, lisinopril or ramipril). ACE inhibitors are used to treat high blood pressure or heart failure. If you have been taking ACE inhibitors, wait for 36 hours after taking the last dose of these group of medicines before you start taking SACUBITRIL VALSARTAN CIPLA (see **Other medicines and SACUBITRIL VALSARTAN CIPLA**).

- If there is a known history of you or your family of a reaction called angioedema (swelling of the face, lips, tongue and/or throat, difficulties in breathing) when taking ACE inhibitors or angiotensin receptor blockers (ARB's) (such as valsartan, telmisartan or irbesartan).
- If you have severe liver disease.
- If you have severe kidney disease.
- If you are pregnant or breastfeeding.
- If you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren.
- If you are currently taking medication that is used for bipolar disorder, called lithium.
- If you are taking medication that assists with increasing passing of urine to treat high blood pressure (diuretics) but increases potassium levels in the body, such as spironolactone, amiloride and triamterene, and potassium supplements.
- If you are taking a fluoroquinolone (an antibiotic).

If any of the above applies to you, do not take SACUBITRIL VALSARTAN CIPLA and talk to your doctor.

Warnings and precautions

Tell your doctor or health care provider before taking SACUBITRIL VALSARTAN CIPLA:

- If you are being treated with an ACE inhibitor or ARB. SACUBITRIL VALSARTAN CIPLA must not be taken after stopping treatment with ACE inhibitors or ARB's until after 36 hours from the time of the last dose of ACE inhibitor or ARB.

- If you are being treated with direct renin inhibitors such as aliskiren. SACUBITRIL VALSARTAN CIPLA should not be taken together with aliskiren if you are diabetic and have severe kidney failure.
- If you have low blood pressure or you are taking any other medicines that reduce your blood pressure or if you are vomiting or having diarrhoea. Blood pressure will have to be corrected before the treatment with SACUBITRIL VALSARTAN CIPLA is started.
- Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys. Before starting treatment and during treatment, your doctor may order blood tests to monitor how your kidneys work.
- Talk to your doctor if you ever had angioedema (swelling of the face, lips, tongue and/or throat, difficulties in breathing).
- If your doctor has advised that you have renal artery stenosis (a kidney artery is narrowed).
- If you have liver disease.

If any of the above applies to you, tell your doctor, pharmacist or healthcare practitioner before you take SACUBITRIL VALSARTAN CIPLA.

Children and adolescents

Do not give SACUBITRIL VALSARTAN CIPLA to children under the age of 18 years. SACUBITRIL VALSARTAN CIPLA has not been tested in children less than 18 years of age.

Other medicines and SACUBITRIL VALSARTAN CIPLA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

SACUBITRIL VALSARTAN CIPLA may interact with other medicines. As a result, the amounts of SACUBITRIL VALSARTAN CIPLA or other medicines in your blood may change. This may stop your medicines from working properly or may make any side effects worse.

ACE inhibitors

Do not take SACUBITRIL VALSARTAN CIPLA with other 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 SACUBITRIL VALSARTAN CIPLA. If you stop taking SACUBITRIL VALSARTAN CIPLA, wait for 36 hours after taking your last dose of SACUBITRIL VALSARTAN CIPLA before starting an ACE inhibitor.

Angiotensin Receptor Blockers (ARB's)

Do not take other medicines used to treat heart failure or lower blood pressure, such as an ARB or aliskiren.

Talk to your doctor if you are taking:

- Statins (cholesterol lowering medication), such as atorvastatin.
- PDE5 inhibitors (used to treat erectile dysfunction or lung hypertension), such as sildenafil.
- Medicine that increases potassium in the blood, such as potassium supplements, salt substitutes containing potassium, potassium sparing medicines and heparin.
- Non-steroidal anti-inflammatory medicines (NSAIDs) including selective cyclooxygenase-2 (COX-2) inhibitors (painkillers), such as diclofenac, ibuprofen.
- Lithium (used to treat psychiatric illness, for example bipolar disorder).
- A diuretic (used to increase the amount of urine production), such as furosemide.

- Nitrates (medicines used to treat chest pain or discomfort), such as nitroglycerine.
- Antibiotics (used to treat bacterial infection), including rifampicin, flouoroquinolones.
- Ciclosporin (used to prevent organ rejection).
- Metformin (medicine used to treat diabetes) as SACUBITRIL VALSARTAN CIPLA may decrease the effect of metformin.
- Fluoroquinolones (antibiotics), such as ciprofloxacin, levofloxacin.

Tell your doctor if you are taking these or any other medicines.

SACUBITRIL VALSARTAN CIPLA with food, drink and alcohol

SACUBITRIL VALSARTAN CIPLA may be taken with or without food. The tablets must be swallowed with a glass of water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- Do not take SACUBITRIL VALSARTAN CIPLA while you are pregnant (see **Do not take SACUBITRIL VALSARTAN CIPLA**).
- Take steps to avoid getting pregnant during treatment with SACUBITRIL VALSARTAN CIPLA. You must use an effective method of contraception. Tell your doctor immediately if you become pregnant.

- Do not breastfeed your baby during the treatment with SACUBITRIL VALSARTAN CIPLA. It is recommended that you do not breastfeed to avoid passing SACUBITRIL VALSARTAN CIPLA to the baby through breast milk.

Driving and using machines

SACUBITRIL VALSARTAN CIPLA can cause dizziness. If you feel dizzy when taking SACUBITRIL VALSARTAN CIPLA, do not drive and do not use any tools or machines.

It is not always possible to predict to what extent SACUBITRIL VALSARTAN CIPLA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SACUBITRIL VALSARTAN CIPLA affects them.

3. How to take SACUBITRIL VALSARTAN CIPLA

Do not share medicines prescribed for you with any other person.

Always take SACUBITRIL VALSARTAN CIPLA exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The target dose is one (1) tablet of SACUBITRIL VALSARTAN 97/103 mg CIPLA twice daily.

The recommended starting dose is one (1) tablet of SACUBITRIL VALSARTAN 24/26 mg CIPLA twice daily for patients currently taking low doses of medicines used to treat high blood pressure (ACE inhibitors or ARB's).

Your doctor will adjust your dose every 3 - 4 weeks you respond well to one (1) tablet of SACUBITRIL VALSARTAN 97/103 mg CIPLA twice daily. Your doctor will need to perform certain tests prior to increasing your dose.

To avoid low blood pressure (hypotension), the recommended starting dose in patients previously using high doses of medicines used to treat high blood pressure (ACE inhibitors or ARB's), is one (1) tablet of SACUBITRIL VALSARTAN 49/51 mg CIPLA twice daily.

SACUBITRIL VALSARTAN CIPLA must not be started for at least 36 hours after stopping treatment with medicines used to treat high blood pressure (ACE inhibitors or ARB's) due to the potential risk of swelling of the face, lips, tongue and/or throat, and difficulties in breathing (angioedema).

If you take more SACUBITRIL VALSARTAN CIPLA than you should

If you accidentally take more than the recommended dose of SACUBITRIL VALSARTAN CIPLA you may be at increased risk of experiencing possible side effects with this medicine (see **section 4**).

Hypotension (low blood pressure) is the most likely symptom of overdose due to the blood pressure lowering effects of SACUBITRIL VALSARTAN CIPLA. Severe dizziness and/or fainting may be experienced and if this is experienced contact the doctor and lie down.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take SACUBITRIL VALSARTAN CIPLA

It is important not to miss a dose of SACUBITRIL VALSARTAN CIPLA. It is advisable to take the medication at the same time each day. If you miss a dose, take the next one at the scheduled time. Do not take a double dose to make up for the missed dose.

If you stop taking SACUBITRIL VALSARTAN CIPLA

Do not stop taking SACUBITRIL VALSARTAN CIPLA without your doctor's advice. Stopping treatment with SACUBITRIL VALSARTAN CIPLA may cause your condition to get worse. Talk to your doctor before you stop taking SACUBITRIL VALSARTAN CIPLA for any reason, particularly if you are experiencing any side effects or you have another illness.

If you have any further questions on the use of SACUBITRIL VALSARTAN CIPLA, ask your doctor or pharmacist.

4. Possible side effects

SACUBITRIL VALSARTAN CIPLA can have side effects.

Not all side effects reported for SACUBITRIL VALSARTAN CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SACUBITRIL VALSARTAN CIPLA, please consult your health care provider for advice.

If any of the following happens, stop taking SACUBITRIL VALSARTAN CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Allergic reaction such as swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing or breathing. These may be signs of angioedema.

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SACUBITRIL VALSARTAN CIPLA. You may need urgent medical attention or hospitalisation.

Other frequent possible side effects that must be reported to the doctor or pharmacist if they become severe:

- Low blood pressure (dizziness, light-headedness).
- High level of potassium in the blood (shown in blood tests).
- Decreased kidney function (kidney impairment).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Cough.
- Dizziness.
- Diarrhoea.
- Low levels of red blood cell (shown in blood tests).
- Headache.
- Acute kidney failure (decreased urination, swelling in your legs, ankles or feet due to fluid retention).
- Weakness.
- Feeling sick (nausea).
- Low blood pressure (dizziness, light-headedness).
- Gastritis (stomach pain, nausea).

- Spinning sensation.
- Low levels of sugar in the blood (shown in blood tests).

Less frequent side effects:

- Dizziness when switching from sitting or lying to standing position.

If any of these side effects get serious tell your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of SACUBITRIL VALSARTAN CIPLA.

5. How to store SACUBITRIL VALSARTAN CIPLA

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

Store in the original package until required for use.

Do not use after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SACUBITRIL VALSARTAN CIPLA contains

SACUBITRIL VALSARTAN 24/26 mg CIPLA: Each film-coated tablet contains 24,3 mg of sacubitril and 25,7 mg of valsartan.

SACUBITRIL VALSARTAN 49/51 mg CIPLA: Each film-coated tablet contains 48,6 mg of sacubitril and 51,4 mg of valsartan

SACUBITRIL VALSARTAN 97/103 mg CIPLA: Each film-coated tablet contains 97,2 mg of sacubitril and 102,8 mg of valsartan.

The other ingredients are:

SACUBITRIL VALSARTAN 24/26 mg CIPLA:

Tablet core

Colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, talc.

Film coating: Opadry 02F540024 Pink

Hypromellose (E464), titanium dioxide (E171), macrogol/PEG (E1521), talc (E553b), iron oxide red (E172) ferrosferric oxide/black iron oxide (E172).

SACUBITRIL VALSARTAN 49/51 mg CIPLA:

Tablet core

Colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, talc.

Film coating: Opadry 02F520038 Yellow

Hypromellose (E464), titanium dioxide (E171), macrogol/PEG (E1521), Talc (E553b), iron oxide yellow (E172), iron oxide red (E172).

SACUBITRIL VALSARTAN 97/103 mg CIPLA:

Tablet core

Colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, talc.

Film coating: Opadry 02F540028 Pink

Hypromellose (E464), titanium dioxide (E171), macrogol/PEG (E1521), Talc (E553b), iron oxide red (E172), ferrosferric oxide/black iron oxide (E172).

What SACUBITRIL VALSARTAN CIPLA looks like and contents of the pack

Film-coated tablets.

SACUBITRIL VALSARTAN 24/26 mg CIPLA: White to off white, modified capsule shaped, biconvex film-coated tablets debossed with “725” on one side and “L” on the other side.

SACUBITRIL VALSARTAN 49/51 mg CIPLA: Light yellow to yellow, modified capsule shaped, biconvex film-coated tablets debossed with “726” on one side and “L” on the other side.

SACUBITRIL VALSARTAN 97/103 mg CIPLA: Light pink to pink, modified capsule shaped, biconvex film-coated tablets debossed with "L727" on one side and plain on the other side.

SACUBITRIL VALSARTAN CIPLA is supplied in pack sizes of 14, 28 and 56 film-coated tablets packed in blister packs (aluminium foil and cold form blister foil), enclosed in a carton with a leaflet.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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