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| Applicant: | Servier Laboratories SA (Pty) Ltd |
| Name:      | Coversyl 5 + 10 mg                |
| Date:      | 29 April 2022                     |

## **PATIENT INFORMATION LEAFLET**

### **Coversyl 5 and 10 mg Film-coated tablets**

Perindopril arginine

Contains sugar (lactose)

Coversyl 5 mg contains 72,58 mg of lactose monohydrate

Coversyl 10 mg contains 145,16 mg of lactose monohydrate

**SCHEDULING STATUS:** S3

#### **Read all of this leaflet carefully before you start taking Coversyl**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or~~ pharmacist, nurse or healthcare provider.
- Coversyl has been prescribed to 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 Coversyl is and what it is used for
2. What you need to know before you take Coversyl
3. How to take Coversyl
4. Possible side effects
5. How to store Coversyl
6. Contents of the pack and other information

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## **1. What Coversyl is and what it is used for**

Each Coversyl 5 mg, film-coated tablet contains 5 mg perindopril arginine salt.

Each Coversyl 10 mg, film-coated tablet contains 10 mg perindopril arginine salt.

Coversyl is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Coversyl is used:

- to treat high blood pressure (hypertension),
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

## **2. What you need to know before you take Coversyl**

### **Do not take Coversyl if**

- you are allergic to perindopril, or to any other ACE-inhibitor or to any of the ingredients of Coversyl (listed in Section 6).
- you are pregnant or trying to become pregnant.
- you are breastfeeding or plan to breastfeed.
- you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE-inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (This rare condition is known as angioedema).
- If you have porphyria.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Coversyl may not be suitable for you,

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- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
- if you are being treated with sacubitril/valsartan, a medicine for heart failure as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see (see Take special care and Taking other medicines and Coversyl)).
- If you take fluoroquinolones (antibiotics).

### **Warnings and precautions**

#### Take special care

- If you are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- If you are to undergo anaesthesia and/or surgery.
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- You have any other health problems, including:  
Kidney disease or if you are receiving dialysis.  
Liver disease.  
Diabetes.  
Heart disease.
- Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- If you have been told by your doctor that you have an intolerance to some sugars.

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- If you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma.
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are taking any of the following medicines used to treat high blood pressure:  
an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
- if you are taking aliskiren (medicines used to treat hypertension).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

- if you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- if you are taking any of the following medicines, the risk of angioedema is increased:
- racecadotril (used to treat diarrhoea),
- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs and for cancer),
- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
- linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (used to treat diabetes).

### **Angioedema**

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE-inhibitors, including Coversyl. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Coversyl and see a doctor immediately (see Possible side effects). (Also see section 4).

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You must tell your doctor if you think that you are (or might become) pregnant. Coversyl is not recommended as it may cause serious harm to your baby (see Pregnancy section).

### **Children and adolescents**

Coversyl is not recommended for children and adolescents.

### **Other medicines and Coversyl**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking Coversyl may change the effect of some medicines, and some medicines may affect how well Coversyl works.

The medicines that may interact with Coversyl include the following:

- Non steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin, a substance presents in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting,
- Lithium medications (used to treat mood swings and some types of depression/mania).
- Potassium-sparing diuretics (e.g. triamterene, amiloride), sources of potassium, like potassium tablets and salt substitutes containing potassium, other medicines which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots, trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria),
- potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg by day,
- other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren or diuretics (medicines which increase the amount of urine produced by the kidneys),

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- medicines used to treat diabetes (tablets and insulin).
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (i.e. tricyclic antidepressants, antipsychotics).
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus).
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors). See section Warnings and precautions
- sacubitril/valsartan (used to treat long-term heart failure). See “Do not take Coversyl and Warnings and precautions”.
- allopurinol (for the treatment of gout).
- procainamide (for the treatment of irregular heartbeat).
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

It is a good idea to remind your doctor of all other medicines you take. Your doctor or pharmacist has more information on medicines that you need to be careful with or avoid while taking Coversyl.

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### **Coversyl with food and drink**

It is preferable to take Coversyl before a meal.

### **Pregnancy and Breastfeeding**

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

#### **Pregnancy:**

Coversyl must not be taken while pregnant. Should you become pregnant or contemplate pregnancy while using Coversyl consult your doctor without delay. The switch to an alternative treatment should be initiated as soon as possible.

You must tell your doctor if you think that you are (or might become) pregnant. Coversyl should not be taken while pregnant or breastfeeding. Should you become pregnant while using Coversyl the medicine must immediately be stopped and consult your doctor without delay.

### **Breastfeeding**

Tell your doctor if you are breastfeeding or about to start breastfeeding. Coversyl is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

### **Driving and using machines:**

When driving vehicles or operating machines it should be taken into account that occasionally dizziness or weariness may occur. If affected, your ability to drive or to operate machinery may be impaired.

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### **Coversyl contains lactose**

Coversyl contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Coversyl.

### **Coversyl contains sodium**

Coversyl contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Coversyl**

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

Always take Coversyl exactly as your doctor has instructed you. You should check with your doctor if you are unsure. Swallow your tablet(s) with a glass of water, preferably in the morning before a meal. The dose of Coversyl you may need each day will be decided and adjusted by your doctor. The usual dosages are as follows:

### **Dosage in high blood pressure**

The recommended dosage is 5 mg orally taken in the morning before breakfast, which can be increased to a single daily dose of 10 mg if necessary, after one month of treatment.

### **Dosage in elderly patients and heart failure**

In elderly patients and patients with heart failure, treatment should be started at a dose of 2,5 mg, which may progressively be increased to 5 mg after one month, then to 10 mg if necessary, depending on kidney function.

### **Use in children and adolescent**

Use in children and adolescent is not recommended.



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**If you take more Coversyl than you should:**

**In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

**If you forget to take Coversyl**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl, take the next dose at the usual time.

Do not take a double dose to make up for the forgotten individual doses.

**If you stop taking Coversyl**

As the treatment with Coversyl is usually life-long, you should discuss with your doctor before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

Coversyl can have side effects.

**Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen, or you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 "Warnings and precautions"),
- severe dizziness or fainting, due to low blood pressure,
- unusual fast or irregular heartbeat, chest pain (angina), heart attack.

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- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis, skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme).
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)

In decreasing order of frequency, side effects can include:

**Frequent**

- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),
- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of tiredness.

• **Less Frequent**

- depression
- mood swings,
- sleep disturbances,

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- dry mouth,
- intense itching or severe skin rashes),
- formation of blister clusters over the skin,
- kidney problems,
- impotence,
- sweating,
- excess of eosinophils (a type of white blood cells),
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- malaise,
- peripheral oedema,
- fever,
- fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.
- acute renal failure,
- dark urine, feeling sick (nausea) or being sick (vomiting), muscle cramps, confusion and seizures. These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion).

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- decreased or absent urine output,
- flushing,
- worsening of psoriasis,
- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.
- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- If you have these symptoms contact your doctor as soon as possible.
- Frequency not known (cannot be estimated from available data): Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **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 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>. By reporting side effects, you can help provide more information on the safety of Coversyl.

### **5. How to store Coversyl**

Store at or below 30 °C in a dry place.

Store all medicine out of reach of children.

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

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Return all unused medicine to your pharmacist.

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

## **6. Content of the pack and other information**

### **What Coversyl 5 mg contains**

The active substance is perindopril arginine. One film-coated tablet contains 3,395 mg perindopril (corresponding to 5 mg perindopril arginine).

### **What Coversyl 10 mg contains**

The active substance is perindopril arginine. One film-coated tablet contains 6,790 mg perindopril (corresponding to 10 mg perindopril arginine).

The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6 000, magnesium stearate, titanium dioxide.

### **What Coversyl 5 mg looks like and contents of the pack**

Coversyl **5 mg** tablets are light-green, rod-shaped film-coated tablets engraved with  on one face and scored on both edges. The tablet can be divided into equal halves.

### **What Coversyl 10 mg looks like and contents of the pack**

Coversyl **10 mg** tablets are Green, round biconvex, film-coated tablet, engraved with  on one face and  on the other face.

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Coversyl is packed into pack sizes of 30 tablets into a polypropylene white tube with a low-density polyethylene flow reducer and a low-density polyethylene white stopper, containing 2 g of white desiccant gel and placed into an outer carton.

**Holder of certificate of registration**

Servier Laboratories South Africa (Pty) Ltd

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Hertford Office Park

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Coversyl 5 mg: A39/7.1.3/0235

Coversyl 10 mg: A39/7.1.3/0236