

# COVERSYL(R) 2.5MG

# COVERSYL(R) 5MG

# COVERSYL(R) 10MG

*perindopril (pronounced per-in-do-pril)*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about COVERSYL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of taking COVERSYL against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.**

You may need to read it again.

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### What COVERSYL is

The name of your medicine is COVERSYL. The medicine contains the active ingredient perindopril arginine. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

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### What COVERSYL is used for

COVERSYL is available only with a doctor's prescription.

COVERSYL lowers high blood pressure, a condition which doctors call hypertension.

Everyone has blood pressure. This pressure helps get your blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have high blood pressure when your blood pressure stays higher than is needed, even when you are calm or relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure. COVERSYL helps lower your blood pressure.

You may be prescribed COVERSYL for heart failure. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Some people develop heart failure after having had a heart attack. However there are also other causes of heart failure.

Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get tired easily after light physical activity such as walking. You may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. In severe heart failure, symptoms may occur even at rest.

COVERSYL helps to treat heart failure. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired, and have less swelling.

You may also have been prescribed COVERSYL if you have coronary artery disease. Coronary artery disease is narrowing of the vessels carrying blood to the heart. In patients with coronary artery disease, COVERSYL has been shown to reduce some of the risks, including heart attacks.

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## BEFORE YOU TAKE COVERSYL

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There are some people who shouldn't take COVERSYL. Please read the list below. If you think any of these situations apply to you or you have any questions, please consult your doctor.

### **Do not take COVERSYL if:**

- \* **you are allergic to perindopril or any of the ingredients listed at the end of this leaflet**
- \* **you are pregnant or trying to become pregnant**
- \* **you are breastfeeding or plan to breast-feed**
- \* **you undergo renal dialysis using polyacrylonitrile membranes**
- \* **you have renal artery stenosis (a problem with the blood vessels to one or both kidneys)**
- \* **you have experienced swelling of the face, tongue, lips or throat either spontaneously or in response to another medicine in the past. (This rare condition is known as angio-oedema)**
- \* **the packaging is torn or shows sign of tampering**
- \* **the expiry date (EXP) on the pack has passed.**

### **Tell your doctor straight away if:**

- \* You become pregnant while you are taking COVERSYL
- \* You are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- \* You are undergoing, or have had an allergic reaction during previous, low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate.

- \* If you are to undergo anaesthesia and/or surgery
- \* if you have recently suffered from diarrhoea or vomiting,
- \* You have any other health problems, including:
  - Kidney disease
  - Liver disease
  - High or low levels of potassium, or other problems with salt balance
  - Diabetes
  - Heart disease

COVERSYL can generally be used safely by elderly people. However reduced kidney function is often found in elderly people and in this case, the starting dose should always be 2.5mg. COVERSYL is not recommended for children.

**If you think any of these situations apply to you, or you have any doubts or questions about taking COVERSYL consult your doctor or pharmacist.**

### **Taking other medicines**

Taking COVERSYL may change the effect of some medicines, and some medicines may affect how well COVERSYL works. You may need different amounts of your medication or to take different medicines. The medicines that may interact with COVERSYL include the following:

- \* Some antibiotic drugs
- \* Some anti-inflammatory drugs
- \* Lithium medications (used to treat mood swings and some types of depression)
- \* Potassium-sparing diuretics, sources of potassium, like potassium tablet and salt substitutes containing potassium.
- \* Some medications used to treat high blood pressure (including diuretics (sometimes called "fluid" or "water" tablets because they increase the amount of urine passed each day), a fast or irregular heartbeat, and other heart conditions

- \* Medicines used to treat diabetes (tablets and insulin).

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

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## HOW TO TAKE COVERSYL

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The dose of COVERSYL you may need each day will be decided and adjusted by your doctor. This will normally be 2.5mg (COVERSYL 2.5MG), 5mg (COVERSYL 5MG) or 10mg (COVERSYL 10MG) once daily for high blood pressure and for people with coronary artery disease or 2.5mg (COVERSYL 2.5MG) to 5mg (COVERSYL 5MG) once daily for heart failure.

**Swallow your tablet(s) with a glass of water, preferably in the morning before a meal.**

### **If you forget to take it**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.**

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

### **How long to take it**

**COVERSYL helps control your blood pressure, or heart failure or coronary artery disease but does not cure it. Continue taking the tablets for as long as your doctor tells you.**

### **If you take too much**

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26 in Australia) if you think you or anyone else may have taken too**

much COVERSYL. Do this even if there are no signs of discomfort or poisoning.

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## WHILE YOU ARE TAKING COVERSYL

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### *Things you must not do*

- \* Do not give COVERSYL to anyone else, even if they have the same condition as you.
- \* Do not use COVERSYL to treat other complaints unless your doctor tells you to.
- \* Do not stop taking COVERSYL or change the dosage, without checking with your doctor.
- \* Do not stop taking your tablets because you are feeling better, unless advised by your doctor.

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## SIDE EFFECTS

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COVERSYL helps most people with high blood pressure, heart failure or coronary artery disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

With COVERSYL, the side effects can include:

- \* cough, often described as dry and irritating
- \* headache, dizziness, vertigo, paraesthesia
- \* tinnitus, vision disturbances
- \* hypotension
- \* feeling tired or lethargic
- \* nausea or stomach pain
- \* muscle cramps
- \* rash, pruritus

These side effects when they occur are usually mild.

**Consult your doctor or pharmacist if you experience any of these or notice anything else that is making you feel unwell.**

Do not be alarmed by this list of possible side effects. You may not experience any of them. Other uncommon side effects have been reported and you should ask your doctor or pharmacist if you want to know more.

**If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:**

- \* Swelling of your lips, face, mouth, tongue or throat.
- \* A fast and irregular heart beat.
- \* Difficulty in breathing
- \* Severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

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## AFTER TAKING COVERSYL

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### *Storage*

Heat and dampness can destroy some medicines. Keep your tablets in the pack until it is time to take them. Keep them in a cool, dry place where it stays below 30 degrees C. Do not store medicines in a bathroom or near a sink. Do not leave them in a car or on a windowsill. Keep them where children cannot reach them. Keep the container tightly closed.

### *Disposal*

If your doctor tells you to stop taking COVERSYL, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

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## What COVERSYL looks like

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COVERSYL 2.5MG are white round convex film-coated tablets containing 2.5mg of perindopril arginine. Supplied in a bottle of 30 tablets.

COVERSYL 5MG are light-green rod-shaped film-coated tablets engraved with a Servier logo on one face and scored on both edges containing 5mg of perindopril arginine. Supplied in a bottle of 30 tablets.

COVERSYL 10MG are green round biconvex film-coated tablets with a Servier logo on one face and a heart on the other face containing 10mg of perindopril arginine. Supplied in a bottle of 30 tablets.

### *Ingredients*

Each tablet of COVERSYL 2.5MG contains 2.5mg of perindopril arginine as the active ingredient and a number of inactive ingredients.

Each tablet of COVERSYL 5MG contains 5mg of perindopril arginine as the active ingredient and a number of inactive ingredients.

Each tablet of COVERSYL 10MG contains 10mg of perindopril arginine as the active ingredient and a number of inactive ingredients.

All tablet doses include lactose, magnesium stearate, maltodextrin, silica - colloidal anhydrous, sodium starch glycollate (type A), macrogol 6000. All tablet coatings include glycerol, hypromellose and titanium dioxide.

The inactive ingredient specific to:

COVERSYL 5MG is: premix for light-green colour coating [copper chlorophyllin (E141ii)]

COVERSYL 10MG is: premix for green colour coating [copper chlorophyllin (E141ii)]

COVERSYL is registered on the Australian register of Therapeutic Goods.

Australian Register Number:

COVERSYL 2.5MG tablets: AUST R 101564

COVERSYL 5MG tablets: AUST R 101568

COVERSYL 10MG tablets: AUST R 101569

***Manufacturer***

COVERSYL is a product discovered by Servier Research International.

It is distributed in Australia by:

Servier Laboratories (Aust) Pty Ltd  
8 Cato Street  
Hawthorn Victoria 3122  
ABN: 54 004 838 500

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