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.

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.

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.

BEFORE YOU TAKE COVERSYL

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 narrowing of the blood vessels to one or both kidneys
- You have narrowing of the main blood vessel leading from the heart
- 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 damaged or shows sign of tampering
- The expiry date (EXP) on the pack has passed.

Tell your doctor straight away if:

- You are pregnant or become pregnant while taking COVERSYL, as it may cause serious harm to your baby.
- 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.
- You are to undergo anaesthesia and/or surgery.
- You have recently suffered from diarrhoea or vomiting.
- You are on a salt restricted diet or use salt substitutes which contain potassium.
- You have an intolerance to some sugars as COVERSYL contains lactose.
- You have any other health problems, including:
  - Kidney disease or if you are on renal dialysis.
  - Liver disease.
  - High or low levels of potassium, or other problems with salt balance.
  - Diabetes.
  - Heart disease.
  - Systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys).

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 (including high dose aspirin, ibuprofen) for pain relief.
- Medicines used to treat mood swings and some types of depression (lithium, tricyclic antidepressants, antipsychotics).
- Potassium-sparing diuretics, sources of potassium, like potassium tablet and salt substitutes containing potassium.
- Heparin (used to thin blood).
- Immunosuppressants (medicines which reduces the activity of the body's natural defences).
- Some medications used to treat high blood pressure (including angiotensin receptor blocker, diuretics (sometimes called “fluid” or “water” tablets because they increase the amount of urine passed each day)
- Vasodilators including nitrates.
- Medicines used to treat diabetes (tablets and insulin).

Medicines which may affect the blood cells, such as allopurinol, proclainamide. 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.

For older people or children

- 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.

HOW TO TAKE COVERSYL

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 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

Taking too much COVERSYL (an overdose) may cause low blood pressure (also known as hypotension). 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 elevated can help. Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

If you think that you or anyone else may have taken too much COVERSYL then act immediately:

- Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 03 474 7000 in New Zealand), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING COVERSYL

Things you must do

Take COVERSYL exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment. Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking COVERSYL.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking COVERSYL.

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.

Things to be careful of

Take care when driving or operating machinery until you know how COVERSYL affects you.

Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery.

SIDE EFFECTS

If you do not feel well while you are taking COVERSYL then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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. These side effects when they occur are usually mild:

With COVERSYL, the side effects can include:

- Cough, often described as dry and irritating, shortness of breath, discomfort on exertion.
- Headache, dizziness, vertigo, pins and needles.
- Changes in the rhythm or rate of the heart beat, fast or irregular heart beat.
- Stroke, myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest).
- Feeling tired or lethargic.
- Tinnitus (persistent noise in the ears), vision disturbances.
- Hypotension, flushing, impaired peripheral circulation, nose bleeds.
- Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation or stomach pain.
- Muscle cramps.
- Rash, pruritus (itching).
- Eosinophilic pneumonia.
- Hepatitis.
- Renal failure.
- Bleeding or bruising more easily than normal caused by a low blood platelet count, frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells, pancytopenia (a rare type of anaemia).
- Decreased blood sugar levels.
Fainting.

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. These side effects are extremely rare but can become serious:

- Swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat.
- A fast and irregular heart beat.
- Purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (a rare condition known as Stevens-Johnson Syndrome).
- Difficulty in breathing
- Severe blisters, skin rash, itching, erythema multiforme or other allergic reactions.

**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.

**WHAT COVERSYL LOOKS LIKE**

- COVERSYL 2.5MG are white round convex film-coated tablets containing 2.5mg of perindopril arginine.
- 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.
- 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.

Thirty (30) tablets are supplied in a white bottle containing desiccants and equipped with a white child-resistant screw-on cap.

**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,
- colloidal anhydrous silica,
- 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 [chlorophyllin-copper complex]
- COVERSYL 10MG is: premix for green colour coating [chlorophyllin-copper complex]

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
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