

COVERSYL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using COVERSYL?

COVERSYL contains the active ingredient perindopril arginine. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. COVERSYL is used to lower high blood pressure, treat heart failure or coronary artery disease. For more information, see Section [1. Why am I using COVERSYL?](#) in the full CMI.

2. What should I know before I use COVERSYL?

Do not use if you have ever had an allergic reaction to perindopril, any other ACE inhibitor or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use COVERSYL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COVERSYL and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use COVERSYL?

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

Swallow your tablet(s) with water, preferably in the morning before a meal. More instructions can be found in Section [4. How do I use COVERSYL?](#) in the full CMI.

5. What should I know while using COVERSYL?

Things you should do	<ul style="list-style-type: none">• Take this medicine exactly as prescribed and remind any healthcare professional you are taking it.• Make sure you drink enough water during
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	<p>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.</p> <ul style="list-style-type: none"> • Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking this medicine.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • 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.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store in a cool dry place away from moisture, heat, and sunlight. Keep your tablets in the pack until it is time to take them. Keep out of reach

	of children. Keep the container tightly closed.
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For more information, see Section [5. What should I know while using COVERSYL?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you do not feel well while you are taking COVERSYL then tell your doctor or pharmacist as soon as possible.

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including COVERSYL. This may occur at any time during treatment. If you develop swelling of your limbs, hands or feet, lips, face, mouth, tongue or throat, a fast and irregular heartbeat, 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 after taking COVERSYL - please seek urgent medical attention. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

COVERSYL®

Active ingredient(s): *perindopril arginine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using COVERSYL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COVERSYL.**

Where to find information in this leaflet:

- [1. Why am I using COVERSYL?](#)
- [2. What should I know before I use COVERSYL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use COVERSYL?](#)
- [5. What should I know while using COVERSYL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using COVERSYL?

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

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.

2. What should I know before I use COVERSYL?

Warnings

Do not use COVERSYL if:

- You are allergic to perindopril, any other ACE inhibitor or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have experienced symptoms such as wheezing, swelling of the face, tongue, lips 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 either spontaneously or, in response to another medicine in the past (a rare condition called angioedema).
- You are pregnant or trying to become pregnant.

- You are breastfeeding or plan to breast-feed.
- You undergo treatments where your blood is treated outside of the body (also known as extracorporeal treatments) that may increase your risk of allergic reactions, treatments such as:
 - renal dialysis or haemofiltration using polyacrylonitrile membranes
 - low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of the blood, using dextran sulphate.
- You are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function.
- You have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
- You are treated with sacubitril/ valsartan a medicine used to treat long-term heart failure as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see also 'Tell your doctor straight away if' and 'What if I am taking other medicines' sections).
- 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 you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments).
- You are to undergo anaesthesia and/or surgery.
- You have recently suffered from diarrhoea or vomiting or are dehydrated.
- 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 are taking lithium (used to treat mania or depression).
- You are taking any of the following medicines used to treat high blood pressure:
 - an 'angiotensin II receptor blocker' (also known as ARBs or sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
 - aliskiren.
 - Sacubitril (available as fixed-dose combination with another medicine valsartan), used to treat long-term heart failure
- You have any other health problems, including:
 - kidney disease, or if you are on renal dialysis
 - aortic stenosis (narrowing of the main blood vessel leading from the heart)

- liver disease
- high or low levels of potassium, or other problems with salt balance
- diabetes
- low blood pressure
- heart disease, including hypertrophic cardiomyopathy (heart muscle disease)
- systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
- are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

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 2.5 mg.

COVERSYL is not recommended for children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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 medications used to treat high blood pressure (including angiotensin receptor blockers), aliskiren (see also 'Do not use COVERSYL if' and 'Tell your doctor straight away if' sections), diuretics (sometimes called 'fluid' or 'water' tablets because they increase the amount of urine passed each day)
- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do not use COVERSYL if' and 'Tell your doctor straight away if' sections)
- Some antibiotics and medicines used to treat infections

- 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, other drugs which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria; and ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection)
- Immunosuppressants (medicines which reduces the activity of the body's natural defences)
- Vasodilators including nitrates
- Medicines used to treat diabetes (tablets and insulin)
- Medicines which may affect the blood cells, such as allopurinol, procainamide
- Baclofen (a medicine used to treat muscle stiffness in diseases such as multiple sclerosis)
- 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)
- Medicines which may increase the risk of angioedema (a severe allergic reaction) such as
 - Mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus)

- Sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure (see also ‘Do not use COVERSYL if’ and ‘Tell your doctor straight away if’ sections).
- gliptins used to treat diabetes (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin, alogliptin).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COVERSYL.

4. How do I use COVERSYL?

How much to take / use

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

When to take / use COVERSYL

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

If you forget to use COVERSYL

COVERSYL should be used regularly at the same time each day.

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.

If you use too much COVERSYL

If you think that you have used too much COVERSYL, you may need urgent medical attention.

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.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using COVERSYL?

Things you should 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.

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including COVERSYL. This may occur at any time during treatment.

Call your doctor straight away if you develop such symptoms described below

- Swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat
- A fast and irregular heartbeat
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using COVERSYL.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COVERSYL affects you.

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.

Looking after your medicine

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°C.

Do not store it in a bathroom, near a sink, in a car or on windowsills.

Keep the container tightly closed.

Keep it where children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

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.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Respiratory and heart</p> <ul style="list-style-type: none">• Difficulty in breathing• A fast and irregular heartbeat <p>Skin</p> <ul style="list-style-type: none">• 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)• Severe blisters, skin rash, itching, erythema multiforme or other allergic reactions• Swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Less serious side effects	What to do
<p>Gastrointestinal</p> <ul style="list-style-type: none"> ● Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort ● Inflammation of the pancreas (pancreatitis) <p>Mouth</p> <ul style="list-style-type: none"> ● Dry mouth ● Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing <p>Kidney and liver related</p> <ul style="list-style-type: none"> ● Kidney problems ● Elevation of bilirubin levels in the blood, increases in liver enzymes ● Kidney disease ● Problems with production or passing of urine ● Concentrated urine (dark in colour), feel or 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.</p> <ul style="list-style-type: none"> ● Hepatitis <p>Respiratory and heart</p> <ul style="list-style-type: none"> ● Cough, often described as dry and irritating, shortness of breath, discomfort on exertion ● Changes in the rhythm or rate of the heartbeat, fast or irregular heartbeat ● Difficulty breathing or wheezing ● Eosinophilic pneumonia ● Myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest) 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Changes in the rhythm or rate of the heartbeat <p>Blood and investigations</p> <ul style="list-style-type: none"> ● High levels in the blood of potassium, urea and/or creatine, low sodium levels in the blood ● Increase in some white blood cells ● Decreased blood sugar levels ● 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) ● Illnesses resulting from a lack of red blood cells <p>Vascular disorders</p> <ul style="list-style-type: none"> ● Hypotension ● Vasculitis ● Flushing 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Impaired peripheral circulation ● Stroke ● Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon) <p>Musculoskeletal</p> <ul style="list-style-type: none"> ● Muscle cramps ● Chest pain ● Aching muscles, muscle tenderness or weakness, not caused by exercise ● Joint pain <p>Nervous system</p> <ul style="list-style-type: none"> ● Headache, dizziness, vertigo, pins and needles ● Mood disturbance, sleep disturbances (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting ● Confusion or hallucinations 	

Less serious side effects	What to do
<p>Skin</p> <ul style="list-style-type: none"> ● Rash, pruritus (itching) ● Excessive sweating ● Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted ● Worsening of psoriasis ● Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body ● Swelling of hands, ankles or feet <p>Eye, ear and nose</p> <ul style="list-style-type: none"> ● Vision disturbances ● Tinnitus (persistent noise in the ears) ● Runny or blocked nose, sneezing, facial pressure or pain ● Nose bleeds <p>Reproductive system</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Erectile dysfunction <p>General</p> <ul style="list-style-type: none"> ● Feeling tired, lethargic or weak ● Fever or high temperature ● Generally feeling unwell ● Falls 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What COVERSYL contains

Active ingredient (main ingredient)	COVERSYL 2.5 contains 2.5 mg of perindopril arginine COVERSYL 5 contains 5 mg of perindopril arginine COVERSYL 10 contains 10 mg of perindopril arginine
Other ingredients (inactive ingredients)	Lactose monohydrate Magnesium stearate Maltodextrin Hydrophobic colloidal anhydrous silica Sodium starch glycollate (type A) Macrogol 6000 All tablet coatings include: Glycerol Hypromellose

	<p>Titanium dioxide</p> <p>The inactive ingredient specific to:</p> <p>COVERSYL 5 is: premix for light-green colour coating [chlorophyllin-copper complex]</p> <p>COVERSYL 10 is: premix for green colour coating [chlorophyllin-copper complex]</p>
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What COVERSYL looks like

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



(Tablet image not actual size)

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



(Tablet image not actual size)

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



(Tablet image not actual size)

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

COVERSYL 2.5: AUST R 101564

COVERSYL 5: AUST R 101568

COVERSYL 10: AUST R 101569

Who distributes COVERSYL

Servier Laboratories (Aust.) Pty. Ltd.

www.servier.com.au

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Phone: 1800 153 590

This leaflet was prepared in July 2023.