

COVERAM[®]

5/5; 5/10; 10/5; 10/10

Perindopril/amlodipine [pronounced per-in-do-pril/ am-load-i-peen]

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about COVERAM.

It does not contain all the available information about this medicine.

Reading this leaflet 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 you taking COVERAM 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 COVERAM IS

The name of your medicine is COVERAM.

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

It also contains the active ingredient amlodipine besilate. Amlodipine belongs to a group of medicines called calcium channel blockers.

Calcium channel blockers do not change the amount of calcium in your blood or bones.

COVERAM has been prescribed for you by your doctor to replace the

separate tablets of perindopril and amlodipine you were taking.

One COVERAM tablet replaces separate tablets of perindopril and amlodipine.

WHAT COVERAM IS USED FOR

You have been prescribed COVERAM if you have high blood pressure, also known as hypertension.

Why COVERAM is used for high blood pressure

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 stressed 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.

The active ingredients in COVERAM, perindopril arginine and amlodipine help lower your blood pressure.

You may also have been prescribed COVERAM if you have coronary heart disease.

Why COVERAM is used for coronary heart disease

Coronary heart disease is narrowing of the vessels carrying blood to the heart.

In patients with coronary artery disease, COVERAM has been shown to reduce some of the risks, including heart attacks.

HOW COVERAM WORKS

COVERAM works by widening your blood vessels, which reduces pressure in the vessel, making it easier for your heart to pump blood around your body

This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

Ask your doctor if you have any questions about why COVERAM has been prescribed for you.

COVERAM is available only with a doctor's prescription.

There is no evidence that COVERAM is addictive.

BEFORE YOU TAKE COVERAM

There are some people who shouldn't take COVERAM. Please read the list below.

If you think any of these situations apply to you or you have any questions, please consult your doctor or pharmacist.

Do not take COVERAM if:

- you are allergic to perindopril or amlodipine, or any of the other ingredients of COVERAM listed at the end of this leaflet.

- you have had an allergic reaction to any other ACE inhibitors or calcium channel blockers

Symptoms of an allergic reaction to COVERAM may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

- are pregnant or trying to become pregnant

COVERAM may affect your developing baby if you take it during pregnancy.

- are breastfeeding or plan to breast-feed

COVERAM passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

- are undergoing 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 are being treated with sacubitril/valsartan, a medicine for heart failure.
- have renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- have aortic stenosis (narrowing of the main blood vessel leaving from the heart).
- have severe hypotension (low blood pressure).
- have unstable angina
Unstable angina is a pain or uncomfortable feeling in the chest that lasts longer than a few minutes or occurs with rest, and may not be relieved with medication.
- have cardiogenic shock which is a sudden and severe drop in blood pressure and blood flow through the body because the heart is not pumping normally.
- have heart failure during the first 28 days after a heart attack (Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. It does not mean that the heart stops working).
- 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.

If you think any of these situations apply to you, or you have any doubts or questions about taking

COVERAM speak to your doctor or pharmacist.

For older people and patients with renal impairment

COVERAM can generally be used safely by elderly people.

Reduced kidney function is often found in elderly people and in this case, the starting dose should always be 2.5 mg of perindopril arginine and 2.5 mg of amlodipine taken as separate tablets.

For children

COVERAM is not recommended for children.

Driving and using machines

COVERAM may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Tell your doctor straight away if:

- you are pregnant or become pregnant while taking COVERAM, 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.
- you are on a salt restricted diet or use salt substitutes which contain potassium.

- you have an intolerance to some sugars as COVERAM contains lactose.
- 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.
- you are treated with immunosuppressant therapy or allopurinol or procainamide.
- 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, severe increase in blood pressure or other heart problems
 - Systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
 - abnormally increased levels of a hormone called aldosterone in your blood (primary hyperaldosteronism).

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

Taking other medicines

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

Taking COVERAM may change the effect of some medicines, and some medicines may affect how well

COVERAM works. You may need different amounts of your medication or to take different medicines.

The medicines that may interact with COVERAM include the following:

- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do Not Take COVERAM If' and 'Tell Your Doctor Straight Away' sections)
- some antibiotic medicines such as erythromycin, clarithromycin and rifampicin
- some medicines used to treat fungal infections such as ketoconazole or itraconazole
- some anti-inflammatory drugs (including high dose aspirin, ibuprofen to relieve pain swelling and other symptoms of inflammation, including arthritis, and gold injections to treat rheumatoid arthritis)
- medicines used to treat mood swings and some types of depression (lithium, tricyclic antidepressants, antipsychotics)
- potassium-sparing medicines (spironolactone, triamterene, amiloride, eplerenone), sources of potassium, like potassium tablet and salt substitutes containing potassium, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- some medications used to treat high blood pressure (including angiotensin receptor blocker, beta-blockers, alpha-blockers) aliskiren (see also 'Do Not Take COVERAM If' and 'Tell Your Doctor Straight Away' sections), or 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)
- muscle relaxants such as baclofen and dantrolene; dantrolene is also used to treat hyperthermia during anaesthesia (symptoms include very high fever and muscle stiffness)
- medicines used to treat epilepsy such as carbamazepine, phenobarbitone, phenytoin or primidone
- St. John's Wort
- medicines which lower your immune system, such as corticosteroids, cyclosporin, tacrolimus or medicines used to treat cancer (including radiation therapy)
- simvastatin (cholesterol lowering medicine)
- tetracosactide, a medicine used to treat adrenal insufficiency
- medicines which may affect the blood cells, such as allopurinol, procainamide
- medicines affecting the part of the nervous system that controls the activities of the heart and blood vessels, including ephedrine, noradrenaline or adrenaline
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer)
- corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis)
- medicines used to treat HIV infection such as indinavir, ritonavir (also called 'protease inhibitors')
- mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus) Sacubitril/valsartan (used to treat long-term heart failure).

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 COVERAM.

HOW TO TAKE COVERAM

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will select a dose when they prescribe COVERAM for you. The usual dose is one tablet once daily.

How to take it

Swallow your tablet(s) with a glass of water.

Grapefruit juice and grapefruit should not be consumed by people who are taking COVERAM. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of COVERAM.

When to take it

Take COVERAM at about the same time each day unless your doctor tells you otherwise.

Taking your tablet at the same time each day will have the best effect. It will also help you remember when to take the tablets.

COVERAM should be taken 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 for

COVERAM helps control your blood pressure and/or treat your coronary heart 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 COVERAM. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING COVERAM

Things you must do

If you become pregnant while you are taking COVERAM, tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking COVERAM.

Tell all doctors, dentists and pharmacists involved with your treatment that you are taking COVERAM.

Take COVERAM exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment.

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
- 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, Toxic Epidermal Necrolysis (TEN))
- severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

If you have stopped treatment with COVERAM due to an allergic reaction you should not start taking COVERAM again.

Things you must not do

- do not give COVERAM to anyone else, even if they have the same condition as you.
- do not use COVERAM to treat other complaints unless your doctor tells you to.
- do not stop taking COVERAM 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 that may help your condition

Some self - help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake
- Diet - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar
- Exercise - regular exercise helps to reduce blood pressure and

helps get the heart fitter, but it is important not to overdo it.

Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of program for you

- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table
- Smoking - your doctor may advise you to stop or at least cut down smoking
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

SIDE EFFECTS

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including COVERAM. This may occur at any time during treatment. If you develop such symptoms described below you should 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
- 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)
- painful red areas, developing large blisters and peeling of layers of skin. This is accompanied by fever and chills
- 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

- difficulty in breathing
- a fast and irregular heart beat.

Talk to your doctor or pharmacist or nurse if you notice any of the following side effects:

Some of the side effects are usually only identified after blood tests.

Very common (may affect more than 1 in 10 people) side effects can include:

- dizziness
- cough, often described as dry and irritating, shortness of breath, discomfort on exertion
- oedema (fluid retention)
- swelling of hands, ankles or feet, joint swelling (ankle swelling).

Common (may affect up to 1 in 10 people) side effects can include:

- chest pain
- nosebleeds
- headache, vertigo, pins and needles
- changes in the rhythm or rate of the heart beat, fast or irregular heart beat
- feeling tired, lethargic or weak
- feeling sleepy (somnolence)
- tinnitus (persistent noise in the ears), vision impairment (including double vision)
- low blood pressure (and related effects), flushing, impaired peripheral circulation, blood vessel inflammation (vasculitis)
- nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, change of bowel habits, stomach pain or discomfort
- dry mouth
- muscle spasms
- fatigue
- rash, pruritus (itching), red raised skin rash
- eczema

- erectile dysfunction
- drowsiness
- chest tightness (dyspnoea), discomfort on exertion.

Uncommon (may affect up to 1 in 100 people) side effects can include:

- conjunctivitis - discharge with itching of the eyes and crusty eyelids, swollen runny eyes
- runny or blocked nose, sneezing, facial pressure or pain
- bleeding or bruising more easily than normal caused by a low blood platelet count (thrombocytopenia)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells (leukopenia)
- hyperglycaemia (high blood sugar levels),
- hypoglycaemia (low blood sugar levels)
- thirst
- numbness or weakness of the arms and legs
- tremor
- numbness, or reduced sense of touch
- high levels in the blood of potassium, urea and/or creatinine, low sodium levels in the blood
- peripheral ischaemia - a condition caused by reduced blood flow to the limbs, hands and feet
- orthostatic hypertension - dizziness on standing up, especially when getting up from a sitting or lying position
- mood disturbance, depression, nervousness, depersonalisation, sleep disturbances (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting
- difficulty breathing or wheezing
- decreased appetite
- difficulty in swallowing
- flatulence or 'passing wind'
- bleeding, tender or enlarged gums

- inflammation of the pancreas (pancreatitis)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- unusual hair loss or thinning
- purpura - unusual bleeding or bruising under the skin, or purple or red-brown spots visible through the skin
- excessive sweating
- increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- skin discolouration
- hypersensitivity reactions, mainly skin reactions, in patients with allergies and asthmatic reactions
- pemphigoid - a skin disease usually affecting older people
- increase in some white blood cells (eosinophilia).
- pollakiuria
- need to urinate during the night
- passing urine more often than usual
- sexual dysfunction
- breast enlargement in men
- fever or high temperature
- kidney problems
- decreased blood sugar levels
- osteoarthritis
- aching muscles, not caused by exercise
- back pain
- generally feeling unwell
- falls
- diplopia, eye pain
- fast, slow or irregular heart beat
- peripheral coldness
- hives or skin rash (urticaria)
- joint pain
- malaise, pain, chills
- blood urea/creatinine increase
- weight gain/weight decrease.

Rare (may affect up to 1 in 1,000 people) side effects can include:

- increased appetite
- confusion, agitation,
- apathy - lack of interest, enthusiasm, concern
- loss of memory
- ataxia - clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech. Unsteadiness when walking
- migraine
- inability to smell
- unusual muscle stiffness causing poor control of movement
- muscle weakness
- blurred vision
- dry eyes
- myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)
- cardiac failure - disease of the heart with heart failure, symptoms include shortness of breath, swelling of the feet or legs due to fluid build-up
- gastritis - inflammation of the stomach where symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions
- 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
- dry skin
- cold and clammy skin
- dermatitis
- elevation of bilirubin levels in the blood, increases in liver enzymes
- hepatitis (liver disease)
- yellowing of the skin and/or eyes, also called jaundice
- muscle twitching
- muscular weakness
- painful or difficult urination
- worsening of psoriasis.

Very rare (may affect up to 1 in 10,000 people) side effects can include:

- hallucination
- cerebrovascular accident
- Quicke's oedema
- Steven Johnson syndrome
- acute kidney disease
- eosinophilic pneumonia
- illnesses resulting from a lack or destruction of red blood cells - (anaemia, pancytopenia)
- illnesses resulting from a lack of white blood cells (agranulocytosis, neutropenia, pancytopenia)
- severe flaking or peeling of the skin
- concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion. If you have these symptoms contact your doctor as soon as possible.

Frequency not known:

- extrapyramidal syndrome - unusual movements, including trembling and shaking of the hands and fingers, rigid posture, mask-like face, slow movements of the body, shuffling unbalanced walk and stiffness of the arms and legs

Consult your doctor, pharmacist or nurse 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, pharmacist or nurse if you want to know more.

AFTER TAKING COVERAM

Storage

Keep your COVERAM tablets in the bottle until it is time to take them.

COVERAM will not keep as well outside its packaging.

Keep your COVERAM tablets in a cool, dry place away from light where the temperature stays below 25°C.

Do not store medicines in a bathroom or near a sink. Do not leave them in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your COVERAM tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

PRODUCT DESCRIPTION

What it looks like

COVERAM 5/5 tablets are white and rod-shaped engraved with 5/5 on one face and the Servier Logo on the other face, supplied in a bottle of 30 tablets.

COVERAM 5/10 tablets are white and square-shaped engraved with 5/10 on one face and the Servier Logo on the other face, supplied in a bottle of 30 tablets.

COVERAM 10/5 tablets are white and triangular-shaped engraved with 10/5 on one face and the Servier

Logo on the other face, supplied in a bottle of 30 tablets.

COVERAM 10/10 tablets are white and round engraved with 10/10 on one face and the Servier Logo on the other face, supplied in a bottle of 30 tablets.

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

Ingredients

Each tablet of COVERAM 5/5 contains 5 mg perindopril arginine and 5 mg amlodipine, and a number of inactive ingredients.

Each tablet of COVERAM 5/10 contains 5 mg perindopril arginine and 10 mg amlodipine, and a number of inactive ingredients.

Each tablet of COVERAM 10/5 contains 10 mg perindopril arginine and 5 mg amlodipine, and a number of inactive ingredients.

Each tablet of COVERAM 10/10 contains 10 mg perindopril arginine and 10 mg amlodipine, and a number of inactive ingredients.

All tablet doses include the inactive ingredients; lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.

COVERAM is registered on the Australian register of Therapeutic Goods.

COVERAM 5/5: AUST R 154438

COVERAM 5/10: AUST R 154439

COVERAM 10/5: AUST R 154440

COVERAM 10/10: AUST R 154441

Manufacturer

COVERAM is a product discovered by Servier Research International.

It is distributed in Australia by:

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