

COVERAM®

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

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 besylate. 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

When you must not take it

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.
- 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.

Do not take COVERAM if you:

- are undergoing renal dialysis using polyacrylonitrile membranes
- have renal artery stenosis (a problem with the blood vessels to one or both kidneys)
- have aortic stenosis (a problem with the left ventricle in your heart)
- have severe hypotension
- 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).

COVERAM is not recommended for use in children, as there are no studies of its effects in children.

Do not take COVERAM if:

- the packaging 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.

Taking other medicines

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:

- other medicines used to treat high blood pressure such as beta-blockers or alpha-blockers
- tetracycline antibiotic drugs such as erythromycin, clarithromycin and rifampicin
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis

- lithium medications (used to treat mood swings and some types of depression)
- potassium-sparing diuretics
- potassium supplements or potassium-containing salt substitutes
- diuretics sometimes called “fluid” or “water” tablets
- medicines used to treat diabetes (tablets and insulin).
- muscle relaxants such as baclofen and dantrolene
- medicines used to treat epilepsy such as carbamazepine, phenobarbital, phenytoin or primidone
- medicines which lower your immune system, such as corticosteroids, cyclosporine or medicines used to treat cancer (including radiation therapy)
- some medicines used to treat some fungal infections

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.

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)
- 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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COVERAM.

COVERAM helps most people with high blood pressure and/or coronary heart 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.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry cough
- headache
- vertigo
- ringing or buzzing in the ears (tinnitus)
- vision disturbances
- feeling light-headed, dizzy or faint (hypotension)
- feeling tired or lethargic (fatigue)
- feeling sleepy (somnolence)
- feeling sick (nausea) or vomiting
- an uncomfortable feeling in the stomach or belching after eating, indigestion (dyspepsia)
- stomach pain
- diarrhoea
- constipation
- flushed skin
- taste disturbances or loss of taste (dysgeusia)
- muscle cramps
- tingling or numbness of the hands or feet, pins and needles (paraesthesia)

- fast or irregular heart beats, also called palpitations
- shortness of breath
- difficulty in breathing or chest tightness (dyspnoea)
- nose-bleeds
- rash, itching (pruritis)
- swelling of hands, ankles or feet (peripheral oedema)

These side effects, when they occur are usually mild. **Speak to your doctor or pharmacist if you experience any of these or notice anything else that is making you feel unwell.**

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).**
- **a fast and irregular heart beat.**
- **severe blisters, skin rash, itching or other allergic reactions.**

These side effects are extremely rare but can become serious.

After taking COVERAM

Storage

Keep your COVERAM tablets in the pack 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 windowsill.

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

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

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

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

Ingredients

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

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

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

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

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

COVERAM is registered on the Australian register of Therapeutic Goods.

COVERAM[®] 5MG/5MG:
AUST R 154438

COVERAM[®] 5MG/10MG:
AUST R 154439

COVERAM[®] 10MG/5MG:
AUST R 154440

COVERAM[®] 10MG/10MG:
AUST R 154441

Manufacturer

COVERAM is a product discovered by Servier Research International.

It is distributed in Australia by:

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