COVERAM®; COVERAM® LD

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 COVERAM?

COVERAM 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. You have been prescribed COVERAM if you have high blood pressure (hypertension). You may also have been prescribed COVERAM if you have coronary heart disease. Coronary heart disease is narrowing of the vessels carrying blood to the heart. For more information, see Section 1. Why am I using COVERAM? in the full CMI.

2. What should I know before I use COVERAM?

Do not use if you have ever had an allergic reaction to perindopril or amlodipine, any other ACE inhibitors or calcium channel blockers, 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 or plan to breastfeed.**

For more information, see Section 2. What should I know before I use COVERAM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COVERAM 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 COVERAM?

Your doctor will select a dose when they prescribe COVERAM for you. The usual dose is one tablet once daily. Swallow your tablet(s) with a glass of water. Grapefruit juice and grapefruit should not be consumed by people who are taking COVERAM.

More instructions can be found in Section 4. How do I use COVERAM? in the full CMI.

5. What should I know while using COVERAM?

Things you should do	• Take this medicine exactly as prescribed and remind any

	healthcare professional you are taking it. • If you have stopped treatment with COVERAM due to an allergic reaction you should not start taking COVERAM again.
Driving or using machines	• COVERAM may affect your ability to drive or use machines. If the tablets make you sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.
Drinking alcohol	• Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	• Store in a cool dry place away from moisture, heat, and sunlight. Keep your tablets in the bottle until it is time to take them. Keep out of reach of children.

For more information, see Section 5. What should I know while using COVERAM? 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 COVERAM 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 COVERAM. This may occur at any time during treatment**. If you develop swelling of your 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 (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 or a fast and irregular heartbeat after taking COVERAM – 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.

COVERAM®; COVERAM® LD

Active ingredient(s): *perindopril arginine/amlodipine besilate*

Consumer Medicine Information (CMI)

This leaflet answers some common questions about COVERAM LD and 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 LD and 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.

Where to find information in this leaflet:

1. Why am I using COVERAM LD or COVERAM?
2. What should I know before I use COVERAM LD or COVERAM?
3. What if I am taking other medicines?
4. How do I use COVERAM LD or COVERAM?
5. What should I know while using COVERAM LD or COVERAM?

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6. Are there any side effects?
7. Product details

1. Why am I using COVERAM LD or COVERAM?

The name of your medicine is COVERAM LD and 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.

What COVERAM LD and COVERAM are used for

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

Your doctor may start your treatment with COVERAM LD, or they may replace the separate tablets of perindopril and amlodipine you were taking with COVERAM. One COVERAM tablet replaces separate tablets of perindopril and amlodipine.

Why COVERAM LD and COVERAM are 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 LD and COVERAM, perindopril arginine and amlodipine help lower your blood pressure.

You may also have been prescribed COVERAM if you have coronary heart disease COVERAM LD is not prescribed for 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 LD and COVERAM work 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 LD or COVERAM have been prescribed for you.

COVERAM LD and COVERAM are available only with a doctor's prescription.

There is no evidence that COVERAM LD or COVERAM are addictive.

2. What should I know before I use COVERAM LD or COVERAM?

There are some people who shouldn't take COVERAM LD or 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.

Warnings

Do not use COVERAM LD or COVERAM if:

- you are allergic to perindopril or amlodipine, or any of the other ingredients of COVERAM LD and 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 LD or 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 LD and COVERAM may affect your developing baby if you take it during pregnancy.
- are breastfeeding or plan to breastfeed. COVERAM LD and COVERAM passes into breast milk and therefore there is a possibility that the breastfed 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 sulfate.

- 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 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).
- 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 LD or COVERAM speak to your doctor or pharmacist.

Tell your doctor straight away if:

- you are pregnant or become pregnant while taking COVERAM LD or 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 LD and COVERAM contain 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 erythematous 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 LD or COVERAM 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

- Do not take COVERAM LD or COVERAM if you are pregnant or trying to become pregnant. COVERAM

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

- Do not take COVERAM LD or COVERAM if you are breastfeeding or plan to breastfeed. COVERAM LD and COVERAM pass into breast milk and therefore there is a possibility that the breastfed baby may be affected.

For older people and patients with renal impairment

- COVERAM LD and COVERAM can generally be used safely by elderly people.
- Reduced kidney function is often found in elderly people and in this case, the dose of COVERAM LD should be 1 tablet every other day. The starting dose of COVERAM should always be 2.5 mg of perindopril arginine and 2.5 mg of amlodipine taken as separate tablets.

For children

- COVERAM LD and COVERAM are not recommended for children.

Driving and using machines

- COVERAM LD and 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.

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 COVERAM LD or COVERAM may change the effect of some medicines, and some medicines may affect how well COVERAM LD and COVERAM works. You may need different amounts of your medication or to take different medicines.

The medicines that may interact with COVERAM LD and COVERAM include the following:

- some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do not use COVERAM LD or COVERAM if' and 'Tell your doctor straight away if' sections)
- some antibiotic medicines such as erythromycin, clarithromycin and rifampicin
- some medicines used to treat fungal infections such as ketoconozole or itracanazole
- 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, 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)

- some medications used to treat high blood pressure (including angiotensin receptor blocker, beta-blockers, alpha-blockers) aliskiren (see also ‘Do not use COVERAM LD or COVERAM if’ and ‘Tell your doctor straight away if’ 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) (see also ‘Do not use COVERAM LD or COVERAM 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 COVERAM LD and COVERAM. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking COVERAM LD or COVERAM.

4. How do I use COVERAM LD or 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 / use

- Your doctor will select a dose when they prescribe COVERAM LD or COVERAM for you. The usual dose is one tablet once daily.
- Follow the instructions provided and use COVERAM LD or COVERAM until your doctor tells you to stop.
- Swallow your tablet(s) with a glass of water.
- Grapefruit juice and grapefruit should not be consumed by people who are taking COVERAM LD or 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 LD or COVERAM.

How long to take it for

- COVERAM LD and COVERAM help control your blood pressure. COVERAM may also treat your coronary heart disease but does not cure it. Continue taking the tablets for as long as your doctor tells you.

When to take / use COVERAM

- Take COVERAM LD or 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 LD and COVERAM should be taken in the morning before a meal.**

If you forget to use COVERAM LD or COVERAM

COVERAM LD or COVERAM 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 you missed.

If you use too much COVERAM LD or COVERAM

If you think that you have used too much COVERAM LD or COVERAM, you may need 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 COVERAM LD or COVERAM?

Things you should do

If you become pregnant while you are taking COVERAM LD or 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 LD or COVERAM.

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

Take COVERAM LD or 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 LD or COVERAM due to an allergic reaction you should not start taking COVERAM LD or COVERAM again.

Things you should not do

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

Driving or using machines

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

COVERAM LD or 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.

Drinking alcohol

Tell your doctor if you drink alcohol. Your doctor may advise you to limit your alcohol intake.

Looking after your medicine

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

COVERAM LD or COVERAM will not keep as well outside its packaging.

Keep your COVERAM LD or 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 LD or 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.

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 COVERAM LD or COVERAM, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

6. Are there any side effects?

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
Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including COVERAM LD or 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	**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.**

Serious side effects	What to do
extremely rare but can become serious: **Respiratory and heart** • difficulty in breathing • a fast and irregular heartbeat **Skin** • 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 • swelling of your extremities (limbs,	

Serious side effects	What to do
hands or feet), lips, face, mouth, tongue or throat	

Less serious side effects

Less serious side effects	What to do
Respiratory and heart • cough, often described as dry and irritating, shortness of breath, discomfort on exertion • chest pain • changes in the rhythm or rate of the heartbeat, fast or irregular heartbeat • chest tightness (dyspnoea) • difficulty breathing or wheezing • fast, slow or irregular heartbeat • myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• 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 **Skin and hair** • rash, pruritus (itching), red raised skin rash • eczema • 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	

Less serious side effects	What to do
• worsening of psoriasis • pemphigoid - a skin disease usually affecting older people • increase in some white blood cells (eosinophilia) • hives or skin rash (urticaria) • 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 • Steven Johnson syndrome • severe flaking or peeling of the skin • swelling of hands, ankles or feet, joint swelling (ankle swelling) • oedema (fluid retention) • Quicke's oedema • unusual hair loss or thinning	

Less serious side effects	What to do
Gastrointestinal • nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, change of bowel habits, stomach pain or discomfort • flatulence or 'passing wind' • inflammation of the pancreas (pancreatitis) • gastritis - inflammation of the stomach where symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions **Mouth** • dry mouth • difficulty in swallowing • bleeding, tender or enlarged gums • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing **Kidney and liver related**	

Less serious side effects	What to do
• pollakiuria • need to urinate during the night • passing urine more often than usual • kidney problems • painful or difficult urination • acute kidney disease • problems with production or passing of urine • 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 can occur with ACE inhibitors. **If you have these symptoms contact your doctor as soon as possible.** • hepatitis (liver disease) • yellowing of the skin and/or eyes, also called jaundice	

Less serious side effects	What to do
Blood, investigations and metabolism • 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) • high levels in the blood of potassium, urea and/ or creatinine • low sodium levels in the blood • eosinophilic pneumonia • illnesses resulting from a lack or destruction of red blood cells - (anaemia, pancytopenia) • illnesses resulting from a lack of white blood	

Less serious side effects	What to do
cells (agranulocytosis, neutropenia, pancytopenia) • elevation of bilirubin levels in the blood • increases in liver enzymes • weight gain • weight decrease • decreased appetite • increased appetite • thirst **Vascular disorders** • low blood pressure (and related effects), flushing, impaired peripheral circulation, blood vessel inflammation (vasculitis) • discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon) • orthostatic hypertension - dizziness on standing up, especially when getting up from a sitting or lying position	

Less serious side effects	What to do
• peripheral coldness • peripheral ischaemia - a condition caused by reduced blood flow to the limbs, hands and feet **Musculoskeletal** • muscle spasms • osteoarthritis • aching muscles, not caused by exercise • back pain • joint pain • unusual muscle stiffness causing poor control of movement • muscle weakness • muscle twitching **Nervous system** • confusion • loss of memory • ataxia - clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/	

Less serious side effects	What to do
or speech. Unsteadiness when walking • migraine • dizziness • headache • pins and needles • feeling sleepy (somnolence) • drowsiness • numbness or weakness of the arms and legs • tremor • numbness, or reduced sense of touch • cerebrovascular accident • 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 **Eye, ear and nose**	

Less serious side effects	What to do
• vision impairment (including double vision) • conjunctivitis - discharge with itching of the eyes and crusty eyelids, swollen runny eyes • diplopia, eye pain • blurred vision • dry eyes • tinnitus (persistent noise in the ears) • vertigo • nosebleeds • runny or blocked nose, sneezing, facial pressure or pain • inability to smell **Reproductive system** • erectile dysfunction • sexual dysfunction • breast enlargement in men **Psychiatric** • mood disturbance, depression, nervousness, depersonalisation, sleep	

Less serious side effects	What to do
disturbances (difficulty sleeping, abnormal dreams), fainting • hallucination • agitation • apathy - lack of interest, enthusiasm, concern **General** • feeling tired, lethargic or weak • fatigue • fever or high temperature • generally feeling unwell • falls • malaise, pain, chills	

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.

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 COVERAM contains

Active ingredient **(main ingredient)**	Each tablet of COVERAM LD 3.5/2.5 contains 3.5 mg perindopril arginine and 2.5 mg amlodipine. Each tablet of COVERAM 5/5 contains 5 mg perindopril arginine and 5 mg amlodipine besilate.

	Each tablet of COVERAM 5/10 contains 5 mg perindopril arginine and 10 mg amlodipine besilate. Each tablet of COVERAM 10/5 contains 10 mg perindopril arginine and 5 mg amlodipine besilate. Each tablet of COVERAM 10/10 contains 10 mg perindopril arginine and 10 mg amlodipine besilate.
Other ingredients **(inactive ingredients)**	Lactose monohydrate Microcrystalline cellulose Colloidal anhydrous silica Magnesium stearate
Potential allergens	Lactose monohydrate

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

What COVERAM LD or COVERAM looks like

COVERAM LD 3.5/2.5 tablets are white and round with no markings.

(Tablet image not actual size)

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.

(Tablet image not actual size)

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.

(Tablet image not actual size)

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.



(Tablet image not actual size)

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.

(Tablet image not actual size)

COVERAM LD: Ten (10), Thirty (30) or Sixty (60) tablets are supplied in a white bottle containing desiccant sachets and equipped with a white child-resistant screw-on cap.

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

COVERAM LD and COVERAM is registered on the Australian register of Therapeutic Goods. Australian Register Numbers:

COVERAM LD 3.5/2.5: AUST R 491505

COVERAM 5/5: AUST R 154438

COVERAM 5/10: AUST R 154439

COVERAM 10/5: AUST R 154440

COVERAM 10/10: AUST R 154441

Who distributes COVERAM

Servier Laboratories (Aust.) Pty. Ltd.

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