

## Package leaflet: Information for the patient

# Coverdine® 5 mg/1.25 mg/5 mg film-coated tablets

**perindopril arginine /indapamide/ amlodipine**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

- What Coverdine is and what it is used for
- What you need to know before you take Coverdine
- How to take Coverdine
- Possible side effects
- How to store Coverdine
- Content of the pack and other information

**1** **What Coverdine is and what it is used for**

Coverdine is a combination of three active ingredients: perindopril, indapamide and amlodipine. It is an anti-hypertensive medicine used in the treatment of high blood pressure (hypertension).

Patients already taking perindopril/indapamide as fixed dose combination and amlodipine from separate tablets may instead receive one tablet of Coverdine which contains the three active ingredients in the same strength.

Each of the active ingredients reduces blood pressure and they work together to control your blood pressure:

- Perindopril belongs to a class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It works by widening the blood vessels, which makes it easier for your heart to pump blood through them.
- Indapamide is a diuretic (which belongs to a class of medicines called sulphonamide derivatives with an indole ring). Diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.
- Amlodipine is a calcium channel blockers (which belongs to a class of medicines called dihydropyridines). It works by relaxing blood vessels, so blood passes through easily.

**2** **What you need to know before you take Coverdine**

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**Do not take Coverdine**

- if you are allergic to perindopril or other ACE-inhibitors, indapamide or other sulphonamides, amlodipine or other dihydropyridines, or any of the other ingredients of this medicine (listed in Section 6),
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (disease of the brain caused by liver illness),
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body),
- if you suffer from heart failure after a heart attack,
- if you have severe low blood pressure (hypotension),

**Parallel Product Authorisation Holder:** Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

**Repackaged by:**

Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland.

**The manufacturer is:**

Servier (Ireland) Industries Ltd, Gorey Road, Arklow - Co. Wicklow - Ireland.

<span></span>
Coverdine is a registered trademark of BIOFARMA.
<span></span>
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## Blind or partially sighted? Is this leaflet hard to see or read? Phone Lexon Pharmaceuticals (Ireland) Limited, Tel: +35318710550 for help.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	TRIPLIXAM, comprimé pelliculé
Bulgaria	TRIPLIXAM, филмирани таблетки
Croatia	TRIPLIXAM, filmom obložene tablete
Cyprus	TRIPLIXAM, επικαλυμμένα με λεπτό υμένιο δισκία
Czech Republic	TRIPLIXAM
Estonia	TRIPLIXAM
Finland	TRIPLIXAM, kalvopäällysteinen tabletti
France	TRIPLIXAM, comprimé pelliculé
Greece	TRIPLIXAM, επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	COVERDINE film-coated tablets
Italy	TRIPLIAM, compresse rivestite con film
Latvia	TRIPLIXAM, apvalkotās tabletes
Lithuania	TRIPLIXAM, plėvele dengtos tabletės
Luxembourg	TRIPLIXAM, comprimé pelliculé
Malta	TRIPLIXAM film-coated tablets
Netherlands	TRIPLIXAM, filmomhulde tabletten
Poland	TRIPLIXAM
Portugal	TRIPLIXAM
Romania	TRIPLIXAM comprimate filmate
Slovakia	TRIPLIXAM, filmom obalené tablety
Slovenia	TRIPLIXAM filmsko obložene tablete

Short sightedness (myopia), vision blurred, decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk. Discoloration, numbness and pain in fingers or toes (Raynaud’s phenomenon).

Changes in laboratory parameters (blood tests) can occur. Your doctor may need to give you blood tests to monitor your condition.

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance,

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

**5** **How to store Coverdine**

<span></span>
Keep this medicine out of the sight and reach of children.
<span></span>
Do not use this medicine after the expiry date which is stated on the carton and tablet container after EXP. The expiry date refers to the last day of that month.
<span></span>
This medicinal product does not require any special storage conditions. For the container of 30 film-coated tablets, the in-use stability after first opening is 30 days.
<span></span>
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

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**6** **Content of the pack and other information**

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**What Coverdine contains**

The active substances are perindopril arginine, indapamide and amlodipine One film-coated tablet of Coverdine 5/1.25/5 mg contains 3.395 mg perindopril equivalent to 5 mg perindopril arginine, 1.25 mg indapamide and 6.935 mg amlodipine besilate equivalent to 5 mg of amlodipine.

The other ingredients are:
Tablet core: Calcium carbonate starch compound: calcium carbonate 90%, maize starch 10%, microcrystalline cellulose (E460), croscarmellose sodium (E468), magnesium stearate (E572), colloidal anhydrous silica, pregelatinised starch.

Tablet film-coating: glycerol (E422), hypromellose 6mPa.s (E464), polyethylene glycol 6000, magnesium stearate (E572), titanium dioxide (E171)

#### What Coverdine looks like and contents of the pack

Coverdine 5/1.25/5 mg are white, oblong, film-coated tablet, 9.75 mm long and 5.16 mm wide, engraved with  on one face and  on the other face.

30 film-coated tablets in polypropylene tablet container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a desiccant.

- if you are taking any of the following medicines, the risk of angioedema is increased:
  - racecadotril (used to treat diarrhea),
  - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs and for cancer).
  - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
  - linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (used to treat diabetes)
- if you are taking any of the following medicines used to treat high blood pressure:
  - an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take Coverdine”.

Your doctor may prescribe you blood tests to check for low sodium or potassium levels or high calcium levels.

You must tell your doctor if you think that you are (**or might become**) pregnant. Coverdine is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see “Pregnancy and breastfeeding”).

Coverdine 100mg tablets

When you are taking Coverdine, you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray).

Coverdine 100mg tablets

Athletes should be aware that Coverdine contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Coverdine 100mg tablets

#### Children and adolescents

Coverdine should not be given to children and adolescents.

Coverdine 100mg tablets

#### Other medicines and Coverdine

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Coverdine 100mg tablets

Do not take aliskiren (used to treat high blood pressure) if you have diabetes or kidney problems.

Coverdine 100mg tablets

You should avoid Coverdine with:

- lithium (used to treat some mental health disorders such as mania, manic depressive illness and recurrent depression),
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria),
- dantrolene (infusion) is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors). See section “Warnings and precautions”,
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take Coverdine” and “Warnings and precautions”,
- other medicines used to treat high blood pressure: angiotensin-converting- enzyme inhibitor and angiotensin receptor blockers.

Coverdine 100mg tablets

Coverdine 100mg tablets

Treatment with Coverdine can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren (see also information under the headings “Do not take Coverdine” and “Warning and precaution”), or diuretics (medicines which increase the amount of urine produced by the kidneys)
- potassium-sparing drugs used in the treatment of heart failure : eplerenone and spironolactone at doses between 12.5mg to 50mg per day,
- anaesthetic medicines,
- iodinated contrast agent,
- bepiridil (used to treat angina pectoris),
- methadone (used to treat addiction),
- medicines used for heart rhythm problems (e.g dofetilide, ibutilide, bretylium, cisapride, diphemamil, procainamide, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- verapamil, diltiazem (heart medicines),
- digoxin or other cardiac glycosides (for the treatment of heart problems),
- antibiotics used to treat bacterial infections (e.g rifampicin, erythromycin, clarithromycin, sparfloxacin, moxifloxacin),
- antifungal medicines (e.g itraconazole, ketoconazole, amphotericin B by injection),
- allopurinol (for the treatment of gout),
- antihistamines used to treat allergic reactions, such as hay fever (e.g mizolastine, terfenadine , astemizole),
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis, and non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. acetylsalicylic acid, a substance presents in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting),
- immunosuppressants (medicines used to control your body’s immune response for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporine, tacrolimus),
- tetracosactide (to treat Crohn’s disease),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis),
- halofantrine (used to treat certain types of malaria),
- baclofen used to treat muscle stiffness in diseases such as multiple sclerosis,
- medicines to treat diabetes such as insulin or metformin,
- calcium including calcium supplements,
- stimulant laxatives (e.g. senna),
- medicines for the treatment of cancer,
- vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- medicines to treat mental health disorders such as depression, anxiety, schizophrenia... (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol),
- pentamidine (used to treat pneumonia),
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV),
- hypericum perforatum (St. John’s Wort),
- trimethoprim (for the treatment of infections),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- nitroglycerin and other nitrates, or other vasodilators that may further reduce blood pressure.

### Coverdine with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Coverdine. 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 Coverdine.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

#### Pregnancy

You must tell your doctor if you think that you are (**or might become**) pregnant.

Your doctor will normally advise you to stop taking Coverdine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Coverdine. Coverdine is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

### Breast-feeding

**Tell** your doctor if you are breast-feeding or about to start breast-feeding. Coverdine is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is new-born, or was born prematurely.

### Driving and using machines

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

### Coverdine contains sodium

Coverdine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## How to take Coverdine

## 3 How to take Coverdine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablet with a glass of water preferably in the morning and before a meal. Your doctor will decide on the correct dose for you. This will normally be one tablet once a day.

### If you take more Coverdine than you should

Taking too many tablets may cause you blood pressure to become low or even dangerously low sometimes associated with nausea, vomiting, cramps, dizziness, sleepiness, mental confusion, oliguria (passing less urine than is normal), anuria (no production or passing of urine). You may feel lightheaded, faint, or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Coverdine tablets.

### If you forget to take Coverdine

It is important to take your medicine every day as regular treatment is more effective. However, If you forget to take a dose of Coverdine, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

### If you stop taking Coverdine

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicinal product.

Coverdine 100mg tablets

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## Possible side effects

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:**

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing, (Uncommon) (may affect up to 1 in 100 people)
- swelling of eyelids, face or lips, (Uncommon) (may affect up to 1 in 100 people)
- swelling of the mouth, tongue and throat, which causes great difficulty breathing, (Uncommon) (may affect up to 1 in 100 people)

- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, Toxic Epidermal Necrolysis) or other allergic reactions, (Very rare) (may affect up to 1 in 10,000 people)
- severe dizziness or fainting, (Common) (may affect up to 1 in 10 people)
- heart attack, (Very rare) (may affect up to 1 in 10,000 people), life-threatening irregular beat (Not known)
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare) (may affect up to 1 in 10,000 people)
- muscle weakness, cramps, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (not known).

In decreasing order of frequency, side effects can include:

- Very common (may affect more than 1 in 10 people): Oedema (fluid retention).

Coverdine 100mg tablets

## 5 Common side effects

Common (may affect up to 1 in 10 people): Headache, dizziness, palpitations (awareness of your heartbeat), flushing, vertigo, pins and needles, visual impairment, double vision, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, change of bowel habit), allergic reactions (such as skin rashes, itching), muscle spasms, feeling of tiredness, weakness, somnolence, ankle swelling.

## 6 Uncommon side effects

Uncommon (may affect up to 1 in 100 people): Mood swings, anxiety, depression, sleep disturbances, trembling, hives, fainting, loss of pain sensation, irregular and/or rapid heartbeat, rhinitis (blocked up or runny nose), hair loss, purpura (red pinpoints on skin), skin discolouration, itchy skin, sweating, chest pain, joint or muscle pain, back pain, pain, feeling unwell (malaise), kidney problems, disorder in passing urine, increased need to urinate at night, increased number of times of passing urine, inability to obtain an erection, fever or high temperature, discomfort or enlargement of the breasts in men, weight increased or decreased, increase in some white blood cells, high potassium levels in the blood, hypoglycaemia (very low blood sugar level), low sodium levels in the blood, vasculitis (inflammation of blood vessels), photosensitivity reaction (change in skin appearance) after exposure to the sun or artificial UVA, blister clusters over the skin, swelling of hands or feet, blood creatinine increased and blood urea increase, fall, dry mouth.

## 7 Rare side effects

Rare (may affect up to 1 in 1000 people): Confusional state, changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin and psoriasis worsening.

Coverdine 100mg tablets

Very rare (may affect up to 1 in 10,000 people): Decreased numbers of white blood cells, decrease in the number of platelets (which causes easy bruising and nasal bleeding), anaemia (decrease in red blood cells), angina pectoris (pains to the chest, jaw and back, brought on by physical effort, and due to problems with the blood flow to the heart), eosinophilic pneumonia (a rare type of pneumonia), swelling of the gums, severe skin reactions including intense skin rash, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), bleeding, tender or enlarged gums, abnormal liver function, inflammation of the liver (hepatitis), severe kidney problems, yellowing of the skin (jaundice), abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, hyperglycaemia (very high blood sugar level), high level of calcium in the blood, stroke possibly secondary to excessive low blood pressure.

Coverdine 100mg tablets

Not known (frequency cannot be estimated from the available data): Hepatic encephalopathy (disease of the brain caused by liver illness), abnormal ECG heart tracing, low potassium levels in the blood, if you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

Coverdine 100mg tablets

Coverdine 100mg tablets

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