



- 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”).

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).

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

#### Children and adolescents

Coverdine should not be given to children and adolescents.

#### Other medicines and Coverdine

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

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

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.

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,
- bepidil (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'.

## 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.

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

## 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).

- 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.

- 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 pinpointes 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.

- 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.

- 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.

- 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.