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**Package leaflet: Information for the user**

**CO-AMILOZIDE 5 mg/50 mg TABLETS**  
**Amiloride hydrochloride and Hydrochlorothiazide**

**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, please ask your doctor or your pharmacist.
- The 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:**

1. What Co-amilozide tablets are and what they are used for
2. What you need to know before you take Co-amilozide tablets
3. How to take Co-amilozide tablets
4. Possible side effects
5. How to store Co-amilozide tablets
6. Contents of the pack and other information

**1. What Co-amilozide tablets are and what they are used for**

The name of your medicine is Co-Amilozide 5 mg/50 mg tablets. The active ingredients are Amiloride hydrochloride and Hydrochlorothiazide. Co-amilozide belongs to a group of medicines called diuretics (water tablets).

This medicine is used to treat:

- high blood pressure
- heart failure
- fluid retention caused by a liver disease called ‘cirrhosis’.

**2. What you need to know before you take Co-amilozide tablets**

**Do not take Co-amilozide tablets if you:**

- are allergic to amiloride hydrochloride and hydrochlorothiazide or to any of the other ingredients in Co-amilozide tablets (listed in section 6)
- have diabetes (a high blood sugar level)
- have been told by your doctor you have high levels of urea, creatinine, potassium or calcium in your blood
- are allergic to a type of antibiotic called sulfonamides, such as sulfamethoxazole
- are allergic to acetazolamide which is a diuretic used to remove fluid from the body and to treat high pressure in the eye (glaucoma), heart problems and sometimes fits or epilepsy
- are allergic to any other ‘thiazide’ water tablet (diuretic)
- are taking potassium sparing water tablets (diuretics) such as eplerenone, spironolactone or triamterene
- are taking medicines containing lithium
- are taking a potassium supplement or medicine containing potassium or you eat potassium-rich foods
- suffer from kidney or liver disease
- have Addison’s disease

Do not take Co-amilozide if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Co-amilozide.

**Warnings and Precautions**

**Talk to your doctor or pharmacist** before taking Co-amilozide tablets if you:

- have been told by your doctor you have high levels of uric acid, cholesterol or triglycerides (a type of cholesterol) in your blood
- are taking digitalis such as digoxin - used for heart failure and abnormal heart beat
- are being given fluids by a tube inserted into one of your veins
- have recently suffered from severe vomiting or diarrhoea
- have systemic lupus erythematosus
- are elderly
- have gout
- have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking this medicine.
- experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking this medicine. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Co-amilozide, seek medical attention immediately.

If you are not sure talk to your doctor or pharmacist before taking Co-amilozide.

**Children and adolescents**

Do not give this medicine to children under 18 years of age as limited data is available.

**Other medicines and Co-amilozide tablets**

**Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Co-amilozide can affect the way some other medicines work. Also some other medicines can affect the way Co-amilozide works.

It is important to tell your doctor or pharmacist if you take:

- angiotensin converting enzyme inhibitors (ACE inhibitors) such as enalapril used to treat high blood pressure or heart problems
- angiotensin II receptor antagonists such as losartan - used to treat high blood pressure or diabetics with kidney damage
- other medicines for high blood pressure
- medicines for diabetes such as insulin or chlorpropamide
- lithium - used for depression
- non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen - used to reduce high temperature (fever), pain or for arthritis
- barbiturates used to help you sleep or to reduce anxiety
- painkillers such as codeine, dihydrocodeine, dextropropoxyphene, diamorphine, morphine, pentazocine and pethidine
- cholestyramine and colestipol - used to treat high cholesterol (hyperlipidaemia)
- steroids - used to treat lots of different conditions such as rheumatism, arthritis, allergic conditions, skin problems, asthma or a type of blood disorder
- ACTH to test whether your adrenal glands are working properly
- medicines injected for allergic reactions such as adrenaline (also known as epinephrine)
- tacrolimus - used after a liver or kidney transplant to prevent rejection
- ciclosporin - used for rheumatoid arthritis or to prevent rejection after a transplant
- ‘non-depolarising’ muscle relaxants such as tubocurarine

- Trilostane - used to treat breast cancer or overactive adrenal glands (such as in Conn’s syndrome, Cushing’s syndrome).

In addition, if you are going to have an operation, make sure the doctor treating you knows you are taking Co-amilozide. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Co-amilozide.

**Tests while you are taking Co-amilozide**

When you are on this medication it may affect some tests on blood or urine samples. Please remind your doctor you are taking Co-amilozide if he or she wants you to have any tests.

If you have diabetes or your doctor suspects you have diabetes, you may need to have some tests before receiving treatment with Co-amilozide.

**Co-amilozide with food, drink and alcohol**

Your doctor may have asked you to change your diet slightly and not to eat certain foods which contain a lot of potassium. These foods include milk, bananas, raisins and prunes. Your doctor will tell you what food you should not eat. If you are unsure about what food you should avoid, ask your doctor before taking Co-amilozide tablets.

Your doctor may have told you that you should keep alcohol intake to a minimum while you are taking Co-amilozide. Alcohol may increase the effects of Co-amilozide so that you feel dizzy or light-headed when you stand up quickly.

**Pregnancy and breast-feeding**

**Pregnancy**

If you are pregnant or breast-feeding think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine. Usually, your doctor will advise you to take another medicine instead of Co-amilozide, as Co-amilozide is not recommended during pregnancy.

This is because Co-amilozide crosses the placenta and its use after the third month of pregnancy may cause potentially harmful foetal and neonatal effects.

**Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Co-amilozide is not recommended for mothers who are breast-feeding.

**Driving and using machines**

This medicine may make you feel tired or dizzy. Do not drive or operate machinery until you have discussed this with your doctor or you know if you are affected.

**Co-amilozide tablets contain Lactose and Sunset yellow**

- Co-amilozide tablets contain **LACTOSE**  
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
- These tablets also contain **SUNSET YELLOW (E110)** which may cause allergic reactions in some people.

**Information on sodium content:**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

**3. How to take Co-amilozide tablets**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should take this medicine by mouth. The amount you take each day will depend on your illness. The number of tablets to be taken will be on the label of your medicine.

The recommended doses are:

**High blood pressure**

The recommended starting dose is half a tablet each day.

SAME SIZE ARTWORK  
540 x 170 mm  
Front

FLAT DIMENSION = 170 x 540mm

FOLDED DIMENSION = 170 x 34mm

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- Your doctor may change your dose to one tablet given each day.
- Your doctor may spread out the dose or give it as a single dose.

**Heart failure**

The recommended starting dose is half a tablet each day.

- Your doctor may change your dose.
- You should not take more than two tablets in a day.

**Fluid retention due to cirrhosis**

The recommended starting dose is one tablet each day.

- Your doctor may change your dose.
- You should not take more than two tablets in a day.

**If you take more tablets than you should**

If you take too much Co-amilozide by mistake, contact your nearest hospital casualty department or doctor immediately. Symptoms of overdose include dehydration and changes in the levels of certain chemicals in the blood.

**If you forget to take the tablets**

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose, to make up for a forgotten dose.

**If you stop taking these tablets**

Do not stop taking these tablets without first talking to your doctor.

Treatment should continue for as long as your doctor feels it is needed.

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

**4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Stop taking Co-amilozide and see a doctor straight away, if you notice any of the following serious side effects that may rarely occur. You may need urgent medical treatment:**

- allergic reactions - the signs may include inflamed blood vessels, difficulties breathing or swallowing, collapse, redness, blisters, peeling skin, muscle pains, chills, a general feeling of being unwell, ulcers in your mouth, eyes or genitals.

**Other side effects include:****Allergic reactions**

- purplish or reddish-brown spots, skin irritation, increased sensitivity to sunlight and a nettle like rash (urticaria).

**Heart and circulation**

- irregular heart beat of your heart that can lead to fainting and dizziness, palpitations
- feeling light headed when you stand quickly
- fast heart beat, chest pains (angina).

**Blood**

- anaemia - signs include unusual tiredness or loss of colour in the lining of the eyes and skin around the eyes
- other blood disorders which can result in high temperature (fever), a sore throat, being unable to stop bleeding from a cut
- changes in the levels of various chemicals in the blood which are usually detected by blood or urine tests.

**Stomach and gut**

- feeling sick (nausea) or being sick (vomiting), indigestion, diarrhoea, constipation, stomach ache and stomach cramps, wind, bloated feeling, hiccups

- bleeding from your gut - signs may include blood in your faeces or a darker colour of faeces
- liver problems such as jaundice - signs may include yellowing of the skin and/or whites of the eyes
- an inflamed pancreas - signs may include feeling sick (nausea) and being sick (vomiting) with pain in the stomach area and back
- swelling of the glands that make saliva
- your mouth may become dry
- a bad taste in your mouth
- lack or loss of appetite
- feeling thirsty.

**Chest**

- difficulty breathing
- blocked nose
- cough.

**Nervous system**

- feeling dizzy, feeling like you are spinning (vertigo), pins and needles
- feeling sleepy, or sometimes feeling that you cannot sleep
- stupor, a type of brain disorder called encephalopathy
- feeling nervous, confused, depressed or restless
- feeling shaky (tremors)
- headache, blackouts.

**Skin and hair**

- flushing, sweating
- rash, itching
- hair loss
- Skin and lip cancer (Non-melanoma skin cancer) (frequency: Not known).

**Eyes or ears**

- an increase in the pressure in the eye which is usually picked up in eye examinations
- 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)
- ringing in the ears.

**Joints and muscles**

- joint pain, pain in the fingers and toes, gout
- neck, shoulder and back pain
- leg ache, muscle cramps.

**Urinary**

- difficulty or pain urinating, an increase in the amount of urine passed
- contractions of the bladder which can lead to an increase in how often you need to pass urine
- kidney disorders which may lead to a reduced amount of urine being passed
- passing urine at night, incontinence.

**Sexual**

- lower sex drive
- impotence.

**Respiratory**

- Very rare - Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

**General/Other**

- a general feeling of being unwell, feeling tired, weakness, dehydration.

**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 Yellow Card Scheme Website:: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Co-amilozide tablets**

- Keep this medicine out of the sight and reach of children
- Containers: Do not store above 25°C. Store in the original container and keep the container tightly closed in order to protect the tablets from light and moisture.
- Blister carton: Do not store above 25°C. Store in the original package and in the outer carton.
- Do not use the medicine after the expiry date which is stated on the carton after ‘EXP’. The expiry date refers to the last day of that month.
- 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 to protect the environment.

**6. Contents of the pack and other information****What Co-amilozide tablets contain**

- The active substance is 5 mg of Amiloride Hydrochloride and 50 mg of Hydrochlorothiazide.
- The other ingredients are: lactose, microcrystalline cellulose, maize starch, magnesium stearate, purified talc, sodium starch glycollate and sunset yellow (E110).

**What Co-amilozide tablet looks like and contents of the pack**

- Co-amilozide tablet are pale, peach coloured, with a breakline on one side and marked ‘BL’ on the other.
- Co-amilozide tablets are available in Securitainers packs of 100 or 500 tablets and Blister packs of 28, 50 or 100 tablets.
- Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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**Co-amilozide 5 mg/50 mg Tablets; PL 17907/0227**

**This leaflet was last revised in March 2022**

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