

## Patient Information Leaflet

### Co-amilozide Tablets BP 5/50mg

**Read all of this leaflet carefully before you start taking Co-amilozide 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in This Leaflet

1. What Co-amilozide is and what it is used for
2. What you need to know before you take Co-amilozide
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4. Possible side effects
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#### 1. What Co-Amilozide is and what it is used for

This medicine contains the active ingredients amiloride hydrochloride and hydrochlorothiazide. Both active ingredients belong to a group of medicines known as diuretics (sometimes described as “water tablets”). Diuretics work by helping the body to dispose of excess water by urination. This medicine is prescribed in certain conditions affecting the heart, liver and other organs (e.g. congestive heart failure, hepatic cirrhosis with ascites) where there is a build-up of excess water in the body. This medicine is also prescribed for the treatment of high blood pressure.

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

##### **Do not take Co-amilozide if:**

- you have previously suffered an allergic reaction to thiazide, a medicine containing amiloride hydrochloride, hydrochlorothiazide or sulphonamide or any of the other ingredients of this medicine (listed in section 6)
- you 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
- you are pregnant, planning to become pregnant or breast feeding
- you have liver or kidney trouble
- you suffer from Addison’s disease or diabetes
- you have been told that you have high levels of urea, creatinine, calcium or potassium in your blood
- you are taking another potassium-sparing diuretic (e.g. eplerenone, spironolactone or triamterene)
- you are taking potassium supplements, or medicine containing potassium or you eat potassium-rich foods
- you are taking medicines containing lithium

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 or nurse before taking Co-amilozide 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
- you are taking digitalis such as digoxin – used for heart failure and abnormal heart beat
- you are being given fluids by a tube inserted into one of your veins
- you have recently suffered from severe vomiting or diarrhoea
- you have Systemic Lupus Erythematosus
- you are elderly
- you have gout
- you 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 Co-Amilozide. This can lead to permanent vision loss, not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- you 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 Co-amilozide
- 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**

This medicine is not suitable for children under 18 years of age.

### **Other medicines and Co-amilozide**

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:

- Potassium supplements
- Non-steroidal anti-inflammatory drugs (NSAIDs e.g. aspirin, ibuprofen) – used to reduce high temperature (fever), pain or for arthritis.
- Medicines used to treat high blood pressure or a heart condition (e.g. captopril, enalapril).
- Lithium, a treatment for depression.
- Barbiturates– used to help you sleep or to reduce anxiety.
- Painkillers such as codeine, dihydrocodeine, diamorphine, morphine, dextropropoxyphene, pentazocine and pethidine
- Trilostane, a medicine used to treat Cushing’s syndrome (an adrenal disorder) and breast cancer.
- Ciclosporin and tacrolimus (immunosuppressant drugs used to prevent organ rejection after transplant surgery).
- Medicines for diabetes such as insulin or chlorpropamide.
- Cholestyramine and colestipol, which are used to reduce the level of fats in the blood.
- Corticosteroids which are used to treat a number of conditions, including asthma, skin disorders, arthritis, allergic conditions, type of blood disorder and rheumatic diseases (e.g. prednisolone).
- ACTH, which is used to test whether your adrenal glands are working properly.
- A pressor amine such as adrenaline, which is used to treat serious allergic reactions.
- Muscle relaxants (e.g. tubocurarine).
- Angiotensin II antagonists, such as Losartan or Olmesartan

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**

You must tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. 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 contains lactose and sunset yellow**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The Sunset yellow (colorant) in the Co-amilozide tablets may cause allergic reactions.

### **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**

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 tablets with a drink of water.

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 usual starting dose is half a tablet each day.
- 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 usual 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 usual 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 Co-amilozide than you should**

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

#### **If you forget to take Co-amilozide**

- If you forget to take your dose, skip the missed dose.
- Take the next dose as normal.
- Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Co-amilozide**

Do not stop taking Co-amilozide without speaking to your doctor.

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

## **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 heartbeat of your heart that can lead to fainting and dizziness, palpitations
- feeling light headed when you stand quickly
- fast heartbeat, 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.
- Frequency 'not known': Skin and lip cancer (non-melanoma skin cancer).

### **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.

**General/Other**

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

**Respiratory**

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

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [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-amilozone****Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date in which is stated on the carton. No special storage condition for this medicinal product.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

Each tablet contains amiloride hydrochloride equivalent to 5mg anhydrous amiloride hydrochloride and 50mg of hydrochlorothiazide.

The tablets also contain lactose monohydrate, calcium hydrogen phosphate dihydrate, maize starch, talc, sodium starch glycolate, magnesium stearate and colour, certolake sunset yellow (E110).

**What Co-amilozone tablets looks like and contents of the pack**

Co-amilozone tablets 5/50mg are pale peach, flat bevelled edge tablets with the company logo on one face and the code 237 and a break line on the reverse.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Pack sizes: 28, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Relonchem Limited  
Cheshire House, Gorsey Lane, Widnes,  
Cheshire, WA8 0RP, UK

Marketing authorisation number: PL 20395/0104

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