Co-amilozide 5/50mg tablets
(amiloride hydrochloride and hydrochlorothiazide)

Read all of this leaflet carefully before you start taking this medicine.
• 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
• If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Co-amilozide tablets belong to a group of medicines called diuretics (water tablets). They may be used for:
• high blood pressure
• congestive heart failure
• liver cirrhosis with fluid retention (oedema) and swelling of the abdomen (ascites).

2 Before you take

Do not take Co-amilozide tablets and tell your doctor if you are:
• allergic (hypersensitive) to amiloride hydrochloride, hydrochlorothiazide, other sulphonamide related drugs, or to any of the other ingredients in Co-amilozide tablets (see section 6).
• under 18 years of age.
or if you have:
• high blood levels of potassium (hyperkalaemia) or other chemicals such as calcium (hypocalcaemia), urea or creatinine
• difficulty passing water
• severe kidney disease
• severe liver failure
• Addison’s disease
• diabetic neuropathy (diabetic nerve damage causing pain, weakness or numbness).

Check with your doctor or pharmacist before taking Co-amilozide tablets if you have:
• liver cirrhosis with swelling of the abdomen (ascites) and abnormally high levels of alkalinity in the body (metabolic alkalosis)
• or have had high levels of acid in the body (metabolic or respiratory acidosis) caused by heart disease or poorly controlled diabetes.

3 How to take

• water retention causing swelling (resistant oedema)
• severe liver disease
• impaired kidney function
• had surgery affecting nerves
• become pregnant or are breast-feeding
• or have had systemic lupus erythematosus (SLE).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:
• diuretics such as spironolactone or triamterene
• blood pressure-lowering drugs (antihypertensives) such as adrenergic blockers and angiotensin II receptor antagonists
• lithium (for some mental illnesses)
• antidiabetic drugs such as insulin or chlorpropamide
• noradrenaline (norepinephrine)
• barbiturates (for sleeping difficulties)
• narcotics e.g. dihydrocodeine
• ACE inhibitors e.g. captopril or enalapril
• corticosteroids e.g. hydrocortisone
• corticosteroids (ACTH)
• tubocurarine (a muscle relaxant)
• non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or naproxen
• antacids (indigestion remedies)
• nephrotoxic drugs e.g. NSAIDs (non-steroidal anti-inflammatory drugs) or captopril (used in some types of cancer)
• cloresten (used to reduce cholesterol)
• tetracycline (used to treat bacterial infections)
• ciclosporin and tacrolimus (used to suppress the immune system)
• digoxin (to treat some heart conditions).

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you are pregnant or if you think that you are. 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.

Sugar intolerance
If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicines, as it contains a type of sugar called lactose.

Diabetic tests
If you are at risk of diabetes or need to have other tests related to diabetes, tell your doctor that you are taking Co-amilozide tablets. The tablets may need to be stopped at least three days before the test, as they can interfere with the results.

Continued over page
For Co-Aamilozide, if you take more than you should 

- **If you** (or someone else) swallow a lot of tablets at the same time, or you take more than you should.

**Tell your doctor or pharmacist if you notice any of the above side effects**; they get worse or if you notice anything not listed.

### How to store

Keep out of the reach and sight of children. Store below 25°C in a dry place. Protect from light.

Do not use Co-Aamilozide after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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.

### Further information

**What Co-Aamilozide tablets contain**

- Each tablet contains the active substances (the ingredients that make the tablets work) amiloride hydrochloride (equivalent to 5mg anhydrous amiloride hydrochloride) and 50mg hydrochlorothiazide.

**What Co-Aamilozide tablets look like and contents of the pack**

Co-Aamilozide tablets are yellow, circular, biconvex, uncoated tablets. Pack size is 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstable, EX32 8NS, UK.

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**3 How to take**

Always take Co-Aamilozide tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

You should not drink alcohol, take potassium supplements or eat foods with a high potassium content (such as bananas) whilst taking this medicine.

**Swallow the tablets.**

**Doses:**

- **High blood pressure:** Usually half a tablet a day, which may be increased to one tablet a day, given as a single or divided dose.

- **Congestive heart failure:** Initially half a tablet a day, which may be adjusted up to a maximum of 2 tablets a day. Your doctor may change your dose depending on your response.

- **Liver cirrhosis with swelling of the abdomen (ascites):** Initially 1 tablet a day as a single dose, which may be adjusted up to a maximum of 2 tablets a day. Your doctor may change your dose depending on your response.

**Elderly:**

The dosage will depend on your kidney function, blood chemical levels and response to treatment. If you are elderly, it is important to take this medicine exactly as prescribed.

**Children:**

Not recommended for children under 18 years old.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you take more than you should.

- **Tell your doctor or pharmacist if you notice any of the above side effects**; they get worse or if you notice anything not listed.

**4 Possible side effects**

Like all medicines, Co-Aamilozide tablets can cause side effects, although not everybody gets them.

**Tell your doctor or pharmacist if you notice any of the following side effects,** they get worse or if you notice anything not listed.

- **Altered balance of fluid or chemicals in the body** (e.g. sodium, potassium, chloride and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain fatigue or cramps, low blood pressure, difficulty passing water, fast heart rate and feeling and being sick.

- **Blood:** altered numbers and types of blood cells causing increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin (you may need a blood test).

- **Metabolism:** dehydration, gout, changes in levels of body chemicals (increased blood potassium, sugar or uric acid or decreased blood sodium), glucose in the urine.

- **Nervous system:** depression, difficulty sleeping or sleepiness, confusion, nervousness and restlessness, dizziness, pins and needles or tingling, near unconsciousness including reduced mental activity and response to stimulation (stupor), feeling of dizziness or spinning (vertigo), tremors and brain disease (characterised by poor concentration, confusion and delirium).

- **Heart:** chest pain (angina), irregular arrhythmias, fast (tachycardia) or pounding (palpitation) heart beats, dizziness on standing due to low blood pressure and inflammation of blood vessels (necrotising angitis).

- **Breathing:** cough, difficulty breathing, fluid in the lungs and lung inflammation (pneumonitis).

- **Stomach and intestines:** feeling of stomach fullness, cramps, stomach irritation or pain, activation of stomach ulcers, bleeding in the stomach or intestines, indigestion, wind, loss or other appetite changes, constipation or diarrhoea, hiccups, feeling or being sick.

- **Liver and pancreas:** inflammation of the pancreas (pancreatitis) and changes in liver function, jaundice (yellow skin or eyes).

- **Skin:** blood spots, bruising and discoloring to the skin (purpura), loss of hair, itching, skin rash, pale or red irregular raised patches with severe itching (hives), flushing, sensitivity of the skin to sunlight or artificial light (e.g. sunbed), sweating and swelling of the salivary glands.

- **Muscles and joints:** joint pain, aching legs and muscle cramps.

- **Urinary and genital:** pain on passing water, getting up in the night to pass water, frequent or copious water production, inability to control bladder movements, bladder pain, impaired kidney function, kidney failure or inflammation, decreased desire for sex and inability to maintain an erection. You should consult your doctor if these are troublesome or continue.

- **Senses:** bad taste, stuffy nose, ringing in the ears, increased pressure in the eyes, visual disturbances and yellow vision.

- **Other:** dry mouth, thirst, allergic (anaphylactic) reactions (itch, swelling, difficulty breathing), back chest neck and shoulder pain, pain in the hands and feet, tiredness, a feeling of general discomfort and illness, weakness, fever, headache and fainting.

**Tell your doctor or pharmacist if you notice any of the above side effects,** they get worse or if you notice anything not listed.

**5 How to store**

Keep out of the reach and sight of children. Store below 25°C in a dry place. Protect from light.

Do not use Co-Aamilozide after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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.

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**6 Further information**

**What Co-Aamilozide tablets contain**

- Each tablet contains the active substances (the ingredients that make the tablets work) amiloride hydrochloride (equivalent to 5mg anhydrous amiloride hydrochloride) and 50mg hydrochlorothiazide.

- The other ingredients are disperse quinoline yellow lake E104, lactose, magnesium stearates, maize starch, microcrystalline cellulose (102) (E460).

**What Co-Aamilozide tablets look like and contents of the pack**

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