**Patient information leaflet**

CO-AMILOZIDE 5/50MG TABLETS

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

- Keep the leaflet. You may need to read it again.
- If you have any other questions, or if there is something you do not understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Never give it to someone else. It may not be the right medicine for 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.

**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
3. How to take Co-amilozide
4. Possible side effects
5. How to store Co-amilozide
6. Contents of the pack and other information

**1. What Co-amilozide is and what it is used for**

Co-amilozide belongs to a group of medicines called diuretics (water tablets). Diuretics work by helping the body to dispose of excess water and urine.

This medicine is used to treat:
- high blood pressure
- congestive heart failure
- liver cirrhosis with fluid retention (oedema) and swelling of the abdomen (ascites)
- heart failure due to heart disease (e.g. congestive heart failure)
- water retention due to liver or kidney disease
- fluid retention due to water retention of the abdomen (ascites)

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

Do NOT take Co-amilozide if you:
- are allergic to amiloride hydrochloride or hydrochlorothiazide or other sulphonamides or any of the other ingredients of this medicine (listed in section 6)
- have difficulty in passing urine
- suffer from Addison’s disease, gout or diabetes
- have kidney or liver disease
- are below the age of 18

**Warnings and precautions**

Talk to your doctor or pharmacist before taking these tablets if you:
- suffer from gestational oedema or hypertension
- have a condition known as systemic lupus erythematosus
- have been told that you have high levels of potassium in your blood (hyper kalaemia)
- are pregnant, planning to become pregnant or breast feeding
- have a lung disease or heart trouble

**Other medicines and Co-amilozide**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:
- potassium supplements
- other potassium-sparing diuretics or ‘water tablets’ used for high blood pressure or fluid retention (e.g. spironolactone, triamterene)
- non-steroidal anti-inflammatory drugs (NSAIDs), used to reduce fever or to relieve pain or the symptoms of arthritis (e.g. aspirin, ibuprofen)
- medicines used to treat high blood pressure or a heart condition (e.g. digoxin, amiodarone and ACE inhibitors, such as captopril and enalapril)
- lithium, ropethoxine, carbamazepine: used for treatment of depression
- barbiturates, which are used to help you sleep or reduce anxiety (e.g. amobarbital)
- narcotic painkillers (e.g. codeine, morphine)
- certain muscle relaxants (e.g. tubocurarine)
- corticosteroids e.g. hydrocortisone
- corticotrophin (ACTH)
- antidiabetic drugs such as insulin or chlorpropamide
- noradrenaline, for serious allergic reactions
- antacids (indigestion remedies)
- cisplatin (used in some types of cancer)
- colestyramine (used to reduce cholesterol)
- tetracycline (used to treat bacterial infections)
- ciclosporin and tacrolimus (used to suppress the immune system)
- lignocaine, flecaainide, atenoloxime, serindole, sotalol
- vitamin D, calcium salts or toremifene
- allopurinol (used to treat gout)
- fluconazole (used to treat fungal infections)
- drinking alcohol while taking this medicine may cause dizziness or light-headedness.

**Driving and using machines**

As this medicine may make you drowsy, you should not drive or operate machinery until you know how the drug affects you.

**Co-amilozide tablets contains lactose & sunset yellow (E110)**

**Lactose -** These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

**Sunset yellow (E110) -** this colouring agent may cause allergic reactions.

**Diabetic tests**

If you are to be tested for 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.

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

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The pharmacist’s label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist. The tablets should be swallowed with a glass of water.

**Adults:**

The number of tablets to be taken is dependent on the disease that you are being treated for. The following are typical doses for each disease state.

**Hypertension:** Usually Co-AMilozide 2.5/25mg (equivalent to half a tablet) given once a day. If necessary, increase to a maximum of one tablet daily (Co-Amilozide 5/50mg).

**Congestive heart failure:** Initially Co-Amilozide 2.5/25mg (equivalent to half a tablet) given once a day, subsequently adjusted if required, but not exceeding 2 tablets (Co-Amilozide 5/50mg) a day.

**Hepatic cirrhosis with ascites:** Initiate therapy with a low dose. A single daily dose of one Co-Amilozide 5/50mg tablet.
may be increased gradually until there is an effective diuresis. Dosage should not exceed two tablets a day.

Use in the elderly: Particular caution is needed in the elderly because of their susceptibility to electrolyte imbalance. The dosage should be carefully adjusted to renal function and clinical response.

Children: This tablet is not recommended for use in children under 18 years of age. All patients, especially elderly patients, should be under regular supervision by their doctor while taking this medicine.

If you take more tablets than you should If you or anyone else has taken too many tablets, contact your nearest hospital casualty department or doctor immediately. Take any remaining tablets with you to show the doctor.

If you forget to take a dose If you forget to take a dose, take the next dose as soon as you remember, then go on as before. If you miss a day, do not take a double dose the following day but continue as prescribed by your doctor.

If you stop taking these tablets Do not stop taking these tablets without first talking to your doctor. If you stop taking your medicine your condition may get worse. Treatment should continue for as long as your doctor feels it is needed.

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

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

If you experience any of the following side effects tell your doctor immediately:
- anaphylactic reaction (serious allergic reaction which causes difficulty in breathing or dizziness)
- skin rashes, itching for the first time, wheezing or swelling of the face, bleeding or easy bruising
- yellowing of your skin or the whites of your eyes caused by liver or blood problems (jaundice)
- muscle pains or cramps
- inflammation of the pancreas (pancreatitis) which causes severe pain in the abdomen and back (may be associated with nausea, vomiting or fever)
- 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
- depression
- irregular (arrhythmia) or fast (tachycardia) heart beats, inflammation of blood vessels (necrotising angiitis)
- inability to control bladder movements, kidney failure or inflammation

Other side effects:
- 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.
- Metabolism: dehydration, gout, changes in levels of body chemicals (increased blood potassium, glucose or uric acid or decreased blood sodium), glucose in the urine.
- Nervous system: difficulty sleeping or sleepiness, confusion, nervousness and restlessness, anxiety, 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), pounding (palpitation) heart beats, dizziness on standing due to low blood pressure and

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, hiccuping, feeling or being sick.

Liver: changes in liver function.

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

Muscles and joints: joint pain, back pain, aching legs.

Urinary and genital: pain on passing water, getting up in the night to pass water, frequent or copious water production, bladder pain, impaired kidney function, decreased desire for sex and inability to maintain an erection.

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

Other: dry mouth, thirst, 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.

Reporting of side effects
If you get any side effects, talk to your doctor, 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 By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-amilozide
Keep all medicines out of the sight and reach of children.
- Do not take this medicine after the expiry date printed on the carton and blister pack or bottle.
- Store in the original container.
- 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 amiloride hydrochloride and hydrochlorothiazide. Each tablet contains 5.60mg amiloride hydrochloride (equivalent to 5mg anhydrous amiloride hydrochloride) and 50mg of hydrochlorothiazide
The other ingredients are lactose monohydrate, calcium hydrogen phosphate dehydrate, maize starch, talc, sodium starch glycolate, magnesium stearate and colour sunset yellow (E110).
See end of section 2 for further information on lactose and sunset yellow (E110).

What Co-amilozide tablets look like and contents of the pack:
Co-Amilozide 5/50mg tablets are pale peach, flat beveled edge circular tablets embossed with A 5/50 with break line on one face and PV on the reverse.

Pack sizes for Co-amilozide are 28, 100, 250, 500 & 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
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Reference: 000410816/04
This leaflet was last revised on August 2016