

PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-Amilozide 2.5mg/25mg & 5mg/50mg 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, ask your doctor or pharmacist.
- 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. 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
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1. What Co-Amilozide Tablets are and what they are used for

The name of your medicine is Co-Amilozide Tablets. This medicine contains two active ingredients, amiloride hydrochloride and hydrochlorothiazide. Amiloride hydrochloride removes excess water and prevents a reduction in potassium levels. Hydrochlorothiazide removes excess water from the body.

Co-Amilozide Tablets comes in two strengths and is used in the treatment heart failure, high blood pressure and fluid retention due to liver disease (especially when it is important to maintain potassium levels).

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, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6)
- are allergic to a type of antibiotic called sulphonamides, such as sulphamethoxazole
- have been told by your doctor that you have high levels of potassium, calcium, urea or creatinine in your blood
- have kidney failure or disease or you are unable to pass water
- have severe liver failure
- are taking potassium supplements or medicines containing potassium or you eat large amounts of potassium rich foods
- you are taking potassium sparing diuretics such as spironolactone or triamterene
- are taking lithium (used to treat manic depression)
- have diabetes (high blood sugar level)
- have Addison's disease (an adrenal glands disease)
- you are pregnant or think you may be pregnant or are breastfeeding
- are under 18 years.

Warnings and precautions

Talk to your doctor before taking

Co-Amilozide Tablets if you:

- are elderly or seriously ill
- have recently suffered from severe vomiting or diarrhoea
- have liver cirrhosis 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.
- have water retention causing swelling (resistant oedema)
- severe liver disease
- impaired kidney function
- you are taking digitalis such as digoxin - used for heart failure and abnormal heart beat
- suffer from gout (a condition where too much uric acid in the body causes joint pains)
- are due to take a glucose tolerance test (this medicine should be discontinued for at least three days before).
- have been told by your doctor you have high levels of uric acid, cholesterol or triglycerides (a type of cholesterol) in your blood
- have severe asthma
- suffer from systemic lupus erythematosus (a disease where the immune system attacks the tissues of the body)
- have had skin cancer or if you develop an unexpected skin lesion during the treatment

- 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 Tablets. 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.

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 Tablets.

Other medicines and Co-Amilozide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect or be affected by treatment with Co-Amilozide Tablets:

- medicines used to treat cancer of the kidney such as aldesleukin
 - non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen - used to reduce high temperature (fever), pain or for arthritis
 - painkillers such as codeine, dihydrocodeine, dextropropoxyphene, diamorphine, morphine, pentazocine and pethidine
 - anion-exchange resins used to reduce cholesterol (e.g. colestyramine and colestipol) – these should be given at least two hours apart
 - anti-arrhythmic medicines used to treat abnormal heart rhythms e.g. quinidine
 - medicines used to treat bacterial infections such as trimethoprim
 - medicines to treat depression (e.g. reboxetine, tricyclic antidepressants and MAOIs)
 - medicines to treat diabetes (e.g. chlorpropamide)
 - carbamazepine, used to treat epilepsy
 - amphotericin and fluconazole, used to treat fungal infections
 - allopurinol, used to prevent gout
 - anti-histamine drugs used to treat allergies e.g. astemizole and terfenadine
 - 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 used to treat high blood pressure (e.g. proazosin, hydralazine, diazoxide)
 - medicines used to treat malaria, such as halofantrine
 - medicines to treat mental illness (e.g. primozide and sertindole)
 - potassium, calcium and vitamin supplements.
 - cardiac glycoside medicines used in heart failure (e.g. digoxin)
 - steroids (e.g. cortisone and hydrocortisone)
 - diuretics such as spironolactone, triamterene or acetazolamide.
 - medicines used to treat Parkinson's disease (e.g. Amantadine, levodopa)
 - hormones or drugs acting on hormones (e.g. trilostane, toremifene, oestrogens)
 - medicines used to suppress the immune system following organ transplant (e.g. ciclosporin and tacrolimus)
 - lithium - used for depression
 - barbiturates used in sedation and anaesthesia
 - 'non-depolarising' muscle relaxants such as tubocurarine used in surgery.
- Tell your doctor if you are going into hospital for an operation
- nitrates, to treat angina
 - carbenoxolone, used to treat stomach ulcers

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Co-Amilozide Tablets with alcohol

If you feel dizzy while taking this medicine then alcohol may make the effects worse.

Pregnancy and breast-feeding

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.

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. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine can make you feel dizzy, reduce alertness or impair your vision. Do not drive or operate machinery if affected.

Co-Amilozide Tablets contains lactose

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

3. How to take Co-Amilozide Tablets

Always take Co-Amilozide Tablets as your doctor has told you. Your doctor will decide the right dose for you. This will be on the pharmacist's label. This medicine should be swallowed whole. The usual starting dose is:

Treatment of high blood pressure:

• one tablet taken once a day. Your doctor may decide to increase your dose up to two tablets a day.

Treatment of heart failure:

• one tablet taken once a day. Your doctor may decide to increase your dose up to four tablets a day.

Treatment of water retention in liver disease:

• two tablets taken once a day. Your doctor may decide to increase your dose up to four tablets a day.

Your doctor may want to monitor your salt levels with regular blood tests, especially if you are elderly or unwell, to check for any possible imbalances.

Children

• This medicine is not recommended for use in children under the age of 18.

If you take more Co-Amilozide Tablets than you should

If you (or anybody else, including a child), takes more Co-Amilozide Tablets than you should then you should contact your nearest hospital casualty department or doctor immediately. Always take the container and this leaflet with you.

If you forget to take Co-Amilozide Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. As can happen with any medicine, a few people may develop an allergic reaction.

If you experience any of the following, stop taking Co-Amilozide tablets and see a doctor straight away:

• **Serious adverse reaction** – 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 that have been reported:

- **Altered balance of fluid or chemicals in the body** (e.g. sodium, potassium, chlorine and magnesium) that may cause feeling of or being sick, weakness, tiredness, irritability, restlessness, confusion and muscle cramps.
- **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, changes in appetite, 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, sleepiness, confusion, reduced response to stimulation (stupor), unconsciousness, nervousness, depression, headaches, dizziness (vertigo), pins and needles, tremors, restlessness, brain disease (characterised by loss of cognitive function, ability to concentrate and subtle personality changes).
- **Senses:** changes in vision such as blurred and yellow vision, bad taste, ringing in the ears (tinnitus), an increase in pressure in the eye, 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).
- **Heart:** chest pain (angina), irregular (arrhythmia), fast (tachycardia) or pounding (palpitation) heart beats, dizziness on standing due to low blood pressure, inflammation of blood vessels

(necrotising angitis),

- **Skin:** rash, irregular raised bumps with severe itching (hives) excessive sweating, hair loss, flushing, sensitivity of the skin to sunlight or artificial light (e.g. sunbeds), bruising and discolouring to the skin (purpura). Frequency 'not known': Skin and lip cancer (Non-melanoma skin cancer).
- **Breathing:** difficulty breathing, hiccups, nasal congestion, cough, fluid in the lungs and lung inflammation (pneumonitis).
- **Stomach and intestines:** Feeling of sickness or being sick, diarrhoea, constipation, abdominal pain and feeling of fullness, passing wind, activation of stomach ulcers, stomach cramps, bleeding in the stomach, inflammation of the salivary glands, and dry mouth
- **Liver and pancreas:** inflammation of the pancreas (pancreatitis), changes in liver function and jaundice (yellow skin or eyes).
- **Muscles and joints:** muscle cramps, leg ache, back pain, joint pain, neck and shoulder ache.
- **Urinary and genital:** getting up in the night to pass water, pain on passing water, frequent or copious water production, inability to control bladder movements, bladder pain, impaired kidney function, kidney failure or inflammation, inability to gain or maintain an erection and a decreased interest in sex.
- **Other:** chest pain, fatigue, feeling unwell, weakness, thirst and fever.

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 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 out of the sight and reach of children.

- Do not store above 25°C. Store in the original container and do not transfer to another container.
- Do not use this 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 medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-Amilozide Tablets contains

The active substances are: amiloride hydrochloride (2.5mg or 5mg) and hydrochlorothiazide (25mg or 50mg). The other ingredients are: lactose, calcium phosphate dibasic, maize starch, pregelatinised maize starch, magnesium stearate, purified water.

What Co-Amilozide Tablets looks like and contents of the pack:

Co-Amilozide 2.5mg/25mg tablets are cream to very pale buff coloured tablets, with a flat bevelled edge, marked CZ 2.5 on one face and CP on the reverse contained in opaque blister packs of 28, 56, 84 and 560 tablets or plastic containers of 100 tablets. Not all pack sizes may be marketed.

Co-Amilozide 5mg/50mg tablets are cream to very pale buff coloured tablets, with a flat bevelled edge, marked CZ 5 on one face and CP on the reverse contained in opaque blister packs of 28, 56, 84 and 560 tablets or plastic containers of 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other sources of information:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product Name	Reference Number
Co-Amilozide 2.5mg/25mg Tablets	PL 29831/0041
Co-Amilozide 5mg/50mg Tablets	PL 29831/0042

This is a service provided by the Royal National Institute of Blind People.

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