

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Co-amilozide 2.5mg/25mg & 5mg/50mg Tablets (Amiloride Hydrochloride + 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 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 Tablets contain a combination of Amiloride and Hydrochlorothiazide (HCT).

Hydrochlorothiazide (HCT) is one of a group of medicines known as thiazide diuretics. These work by increasing the volume of urine you produce, therefore reducing the water content of your blood and in turn the volume of blood circulating in your body. Hydrochlorothiazide can cause potassium to be filtered out of the blood, which can sometimes cause the level of potassium in the blood to fall too low.

Amiloride is one of a group of medicines known as potassium-sparing diuretics. Amiloride is a weaker diuretic that causes potassium to be retained in the body. It is used in combination with the Hydrochlorothiazide in this medicine to prevent the amount of potassium in the blood from falling too low.

Amiloride + Hydrochlorothiazide Tablets (referred to as Co-amilozide throughout this leaflet) are used for the treatment of high blood pressure (hypertension), heart failure, scarring of the liver caused by long-term liver damage (hepatic cirrhosis) & fluid retention.

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

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

- You are allergic to Amiloride, Hydrochlorothiazide, other Sulfonamide-derived medicines or any of the other ingredients of this medicine (See Section 6 “Contents of the pack and other information”)
- If you have high levels of potassium in the blood [hyperkalaemia] (especially if you are elderly, diabetic or suffer from liver or heart failure), are currently taking potassium-sparing diuretics such as spironolactone or triamterene (see “Other medicines and Co-amilozide”), potassium supplements or potassium-rich foods (unless you have severely low levels of potassium and you are being carefully monitored)
- You suffer from kidney failure, kidney disease or other kidney problems such as anuria (failure of the kidneys to produce urine)
- You suffer from severe liver failure or severe liver disease (hepatic cirrhosis)
- You suffer from Addison's disease
- You have high levels of calcium in the blood (hypercalcaemia). Treatment with Co-amilozide should be discontinued before carrying out tests for parathyroid function
- You are taking lithium (see “Other medicines and Co-amilozide”)
- You suffer from diabetes (see “Warnings and precautions” section) or diabetic neuropathy (kidney disease or damage that can occur in people with diabetes)
- You have high levels of urea or creatinine in the blood (may be a sign of kidney problems)

## Warnings and precautions

### Talk to your doctor before taking Co-amilozide:

- 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 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, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- If you have high levels of potassium in the blood [hyperkalaemia] (especially if you are elderly, diabetic or suffer from liver, heart or kidney failure)
- If you are currently taking potassium supplements or potassium-rich foods (unless you have severely low levels of potassium and you are being carefully monitored)
- If you suffer from kidney problems, including abnormally high levels of blood urea nitrogen (uraemia)
- If you show signs of fluid and electrolyte imbalance [symptoms include dry mouth, weakness, lack of energy, drowsiness, restlessness, fits, confusion, muscle pain, cramps, low blood pressure (hypotension), decreased production of urine (oliguria), faster heartbeat (tachycardia), feeling sick (nausea) or being sick (vomiting), particularly if you are elderly or receiving long-term treatment]:
  - Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia), particularly if you are elderly or suffering from severe heart failure
  - Abnormally high alkalinity of the blood and body fluids (hypochloraemic alkalosis)
  - Abnormally low levels of potassium in the blood (hypokalaemia)
  - An abnormally low level of magnesium in the blood (hypomagnesaemia)
- If you suffer from liver problems or liver disease
- If you have an abnormally high level of uric acid in the blood (hyperuricaemia)
- If you suffer from gout (pain and swelling in one or more joints)
- If you are diabetic. The status of kidney function should be determined before Co-amilozide is given to known or suspected diabetics. Co-amilozide should be discontinued for at least 3 days before giving a glucose-tolerance test as HCT may impair the results. Diabetes may be caused or aggravated by treatment with Co-amilozide. Dosage adjustment of anti-diabetic medicines, including insulin, may be required (see "Other medicines and Co-amilozide")
- If you have increased level of fats (cholesterol and triglyceride) in your blood
- If you suffer from or have previously suffered from increased acidity in the blood (acidosis)
- If you suffer from Systemic Lupus Erythematosus (long-term inflammation of skin)
- If 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

### 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.

#### Medicines which **may interact with or be affected by** Co-amilozide:

- Aldesleukin, a medicine used to treat cancer of the kidney
- Medicines used to increase frequency of urination e.g. spironolactone, triamterene, bendroflumethiazide, acetazolamide (diuretics)
- Medicines used to treat Parkinson's disease e.g. amantadine, levodopa
- Hormonal medicines e.g. toremifene, oestrogens
- Potassium supplements, calcium and vitamin D
- Medicines used to treat heart failure e.g. digoxin (cardiac glycosides)
- Lithium, a medicine used to treat mood disorders (anti-psychotic)
- Medicines used to treat diabetes e.g. insulin, chlorpropamide (anti-diabetics)
- Diazoxide, a medicine used to treat a low blood sugar level
- Halofantrine, a medicine used to treat malaria
- Medicines to treat mental illness e.g. primozide and sertindole

- Carbamazepine, a medicine used to treat epilepsy
- Amphotericin and fluconazole, medicines used to treat fungal infections
- Allopurinol, a medicine used to prevent gout
- Medicines used to treat allergies e.g. astemizole and terfenadine (anti-histamines)
- Medicines used to treat certain rheumatic disorders such as aspirin or ibuprofen (Non-Steroidal Anti-Inflammatory Drugs – NSAIDs)
- Medicines used to reduce the body's immunity when receiving organ transplant e.g. ciclosporin, tacrolimus (immunosuppressants)
- Medicines used to treat Cushing's syndrome e.g. trilostane
- Medicines used to treat high blood pressure such as methyldopa, enalapril (ACE [Angiotensin-Converting Enzyme] inhibitors). Co-amilozone should be discontinued for 2-3 days before starting treatment with an ACE inhibitor
- Other medicines used to treat high blood pressure such as losartan (angiotensin II receptor antagonists), prazosin (alpha blockers), hydralazine (beta blockers), verapamil (calcium channel blockers)
- Medicines used to lower cholesterol e.g. cholestyramine, colestipol - these should be given at least 2 hours apart
- Medicines used to reduce inflammation such as cortisone, hydrocortisone (corticosteroids)
- Corticotropin (AdrenoCorticoTropic Hormone - ACTH)
- Medicines used to treat serious allergic reaction (anaphylaxis) such as epinephrine (adrenaline) and noradrenaline (sympathomimetics)
- Carbenoxolone, a medicine used to treat stomach ulcers
- Tubocurarine, tizanidine, muscle relaxants
- Nitrates, to treat angina
- Alprostadil, a medicine used to treat erectile dysfunction (vasodilator)
- Barbiturates, medicines used in sedation and anaesthesia
- Quinidine, a medicine used to treat abnormal heart rhythms (anti-arrhythmic)
- Trimethoprim, a medicine used to treat bacterial infections
- Medicines to treat depression e.g. reboxetine, tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs)
- Analgesic medicines used to relieve pain
- Treatment with Co-amilozone should be stopped before having a parathyroid function test or kidney function test as it may affect the results

### **Co-amilozone and alcohol**

During treatment with Co-amilozone, it is advisable not to drink alcohol as this may cause you to become dizzy or faint on standing up from a resting position.

### **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-amilozone, as Co-amilozone is **not** recommended during pregnancy. This is because Co-amilozone crosses the placenta and its use after the third month of pregnancy may cause potentially harmful foetal and neonatal effects.

#### **Breastfeeding**

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

### **Driving and using machines**

You may have a headache or problems with your vision, or you may feel weak, tired, dizzy, dazed or experience a feeling of "spinning" (vertigo), whilst taking this medicine. If any of these symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

### **Co-amilozone contains lactose**

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

### **Co-amilozide contains wheat starch**

This medicine only contains very low levels of gluten and is very unlikely to cause problems if you have coeliac disease.

One Co-amilozide 2.5/25mg tablet contains no more than 41.5 micrograms of gluten.

One Co-amilozide 5/50mg tablet contains no more than 83 micrograms of gluten.

If you have wheat allergy (different from coeliac disease) you should not take this medicine.

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

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

- These tablets are to be taken orally as a single dose in the morning.
- These tablets should be taken independently of meals and with a generous amount of fluid.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

### **The recommended dose for adults is:**

#### **To treat high blood pressure:**

Initially, a single daily dose of Co-amilozide 2.5mg/25mg should be taken.

If necessary, the dose may be increased to Co-amilozide 5mg/50mg taken as a single daily dose or in divided doses.

Co-amilozide may be used alone or with other medicines used to treat high blood pressure, but the dosage of the other medicines may need to be lowered to reduce the risk of an excessive drop in blood pressure.

#### **To treat heart failure:**

Initially, a single daily dose of Co-amilozide 2.5mg/25mg. This may be adjusted if required, but should not exceed four Co-amilozide 2.5mg/25mg tablets daily. A reduction in dose may be attempted for maintenance treatment.

#### **To treat liver disease with an excessive accumulation of body fluid:**

Treatment should be started with a low dose. A single daily dose of two Co-amilozide 2.5mg/25mg tablets may be increased gradually, but dosage should not exceed four Co-amilozide 2.5mg/25mg tablets a day. Maintenance doses may be lower than those required initially. Dose reduction should be attempted once the patient's weight is stabilised.

#### **Elderly patients:**

The dose may need to be adjusted depending on how well your kidneys work and how well you respond to treatment with this medicine.

#### **Use in children:**

Co-amilozide Tablets are **not** recommended for use in children under 18 years of age.

#### **If you take more Co-amilozide than you should**

If you accidentally take too many tablets, contact your doctor or nearest emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

**The symptoms of overdose include:** coma, breathing difficulties. The most common symptoms of overdose are dehydration and electrolyte imbalance:

- abnormally low levels of potassium in the blood (hypokalaemia)
- abnormally low level of the chloride ion in the blood (hypochloraemia)
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia)

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

Take it as soon as you remember, unless it is nearly time for your next dose.

If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

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

It is important that you keep taking Co-amiloride for as long as your doctor has told you to. **Do not** stop taking the tablets even though you may feel better. **Do not stop** or change your treatment before talking to your doctor.

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

#### **4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Seek medical advice immediately if you develop the following symptoms:**

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Severe blistering of the skin, mouth, eyes and genitals (Toxic Epidermal Necrolysis) [TEN]
- 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)

#### **Side effects (frequency not known)**

- Skin and lip cancer (non-melanoma skin cancer)
- Headache
- Feeling of weakness
- Tiredness (fatigue), mental numbness (stupor), sleepiness or drowsiness (somnolence)
- Generally feeling unwell (malaise),
- Fainting (syncope), dizziness, vertigo (sensation of whirling and loss of balance, feeling giddy)
- Disrupted heart rhythm (arrhythmias), faster heartbeat (tachycardia), feeling your heartbeat (palpitations), partial heart block (electrical pulses that control the beating of the heart are disrupted) developing into complete heart block
- Digitalis Toxicity (a poisoning that occurs when you take too much digitalis [also known as digoxin or digitoxin], a medication used to treat heart conditions)
- Low blood pressure (hypotension)
- Chest pain (angina pectoris)
- Loss of appetite (anorexia), disturbed sense of taste, appetite changes, inflammation of the salivary glands (sialadenitis)
- Feeling or being sick (nausea, vomiting)
- Diarrhoea
- Constipation
- Stomach pain, cramping or irritation, feeling of a full stomach, feeling bloated/wind (flatulence), hiccups, activation of pre-existing stomach ulcer, indigestion (dyspepsia)
- Inflammation of the pancreas (pancreatitis), bleeding in the stomach and intestine
- Thirst, dehydration, dry mouth
- Increased blood levels of potassium
- Electrolyte imbalance (electrolytes are minerals such as calcium, chloride, magnesium, phosphate, potassium, and sodium. For the body to function properly, certain minerals need to be maintained in an even balance)
- Low blood levels of sodium (hyponatraemia)
- Pain and swelling in one or more joints (gout)
- Rash, severe itching (pruritus), skin rashes with the formation of wheals (urticaria)
- Flushing
- Excessive sweating (diaphoresis), fever
- Leg ache, muscle cramps, chest/back/joint pain, neck/shoulder ache, pain in arms &/or legs
- Tingling or numbness in the hands or feet (paraesthesia)
- Difficulty in sleeping (insomnia), restlessness
- Nervousness
- Shakiness (tremors)
- Mental confusion
- Depression
- Shortness of breath or difficulty in breathing (dyspnoea), pneumonitis (inflammation of the lungs), excess collection of watery fluid in the lungs (pulmonary oedema), cough, blocked nose (nasal congestion)

- Visual disturbances including a condition in which all objects appear to have a yellowish tinge to them (xanthopsia), blurred vision, increased pressure inside the eye
- Inability to maintain an erection (impotence) which occurs early in the course of treatment and is reversible on withdrawal of treatment, decreased libido
- Painful urination (dysuria), a need to wake and pass urine at night (nocturia), unintentional passing of urine (incontinence), increased production of urine (polyuria), urinary frequency, bladder spasm, glucose in the urine (glycoscuria)
- Kidney problems including kidney failure, inflammation of the kidney (interstitial nephritis)
- Liver problems including yellowing of the skin or whites of the eyes (jaundice)
- Hair loss (alopecia)
- Disorder of the brain (encephalopathy)
- Ringing in the ears (tinnitus)
- Increased blood sugar levels (hyperglycaemia)
- High level of uric acid in the blood (hyperuricaemia)
- Abnormally low levels of potassium in blood (hypokalaemia)
- High levels of calcium in the blood (hypercalcaemia)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- Reduction in blood cells which may increase the risk of bleeding or bruising (thrombocytopenia) and/or make infections more likely (leucopenia, neutropenia, agranulocytosis)
- Inflammation and damage of the blood vessel walls that also affects the skin (necrotising angiitis, vasculitis, purpura)
- Acute Respiratory Distress Syndrome (ARDS) (signs include severe shortness of breath, fever, weakness, and confusion) – very rare side effect.

### 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 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-amilozide

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last date of that month.
- Store below 25°C. Store in the original package in order to protect from light.
- 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 contains:

- Each 2.5/25mg tablet contains 2.5mg of Amiloride and 25mg of Hydrochlorothiazide
- Each 5/50mg tablet contains 5mg of Amiloride and 50mg of Hydrochlorothiazide

**The other ingredients are:** wheat starch, lactose anhydrous, gelatin, talc and magnesium stearate.

#### What Co-amilozide looks like and contents of the pack:

- Co-amilozide 2.5/25mg tablets: slightly yellow, round, scored tablets with a bevelled edge, with an approximate diameter of 7mm with the code "EZ/3" on one side
- Co-amilozide 5/50mg tablets: slightly yellow, round, scored tablets with a bevelled edge, with an approximate diameter of 8.5mm with the code "EV/7" on one side

#### Co-amilozide is available in:

Co-amilozide tablets are available in blister packs of 28 tablets.

#### Marketing Authorisation Holder:

Tillomed Laboratories Ltd.  
220 Butterfield  
Great Marlings  
Luton  
LU2 8DL  
United Kingdom

**Manufacturer<sup>1</sup>:**

Kleva Pharmaceuticals S.A.  
189 Parnithios Ave  
13675 Acharnai-Attiki  
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**Tillomed Laboratories Limited**

220 Butterfield  
Great Marlings  
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**Product Licence Numbers:**

- Co-amilozide 2.5mg/25mg Tablets: PL 11311/0522
- Co-amilozide 5mg/50mg Tablets: PL 11311/0523

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<sup>1</sup> Only actual manufacturer stated on printed leaflet.