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PACKAGE LEAFLET: INFORMATION FOR THE USER

CO-AMILOZIDE TABLETS BP 5/50mg

Amiloride Hydrochloride & 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 gets serious, or if you notice any side effect 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
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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 BP 5/50mg. They contain the active ingredient Amiloride Hydrochloride and Hydrochlorothiazide. Amiloride Hydrochloride is a potassium sparing diuretic. Hydrochlorothiazide is a thiazide diuretic. The two are commonly prescribed together to get rid of excess water from the body without also losing potassium.

Co-amilozide Tablets may be used for:

- high blood pressure
- congestive heart failure.
- Hepatic cirrhosis with ascites (chronic disease of the liver characterized by the replacement of normal tissue with fibrous tissue and the loss of functional liver cells), where there is a build-up of excess water in the body.

2. BEFORE YOU TAKE CO-AMILOZIDE TABLETS

Do not take Co-Amilozide Tablets if you:

- are allergic (hypersensitive) to the active ingredients or to any of the other ingredients of Co-Amilozide Tablets (see section 6)
- are allergic to Sulphonamide related drugs (a type of antibacterial drug)
- have been told you have high blood potassium or calcium levels
- are taking potassium supplements, or another potassium sparing diuretic (e.g. Spironolactone or Triamterene) or you are on a high potassium diet
- have anuria (inability to urinate due to failure in the function of kidneys)
- have severe kidney disease or failure
- have diabetic nephropathy (progressive kidney disease due to long standing diabetes mellitus)
- have severe liver disease or failure
- have precoma (state preceding coma) associated with liver disorder
- have Addison's disease (underactive adrenal glands)
- are receiving treatment with Lithium.
- are under 18 years.

Take special care with Co-Amilozide Tablets and contact your doctor before taking these tablets if you:

- are diabetic or are going to be tested for diabetes, or have gout (severe pain and swelling in the joints)
- have kidney, heart, lung or liver problems
- have too much potassium in the blood (hyperkalaemia) or other disturbances of blood chemicals
- have a condition known as systemic lupus erythematosus (SLE), an autoimmune disease
- need an operation.
- suffer from porphyria (a disease of blood proteins that effect the skin, gut and nervous system)

Taking other medicines

You must tell your doctor if you are taking or have recently taken any of the following medicines as they may interact with your Co-Amilozide Tablets.

Examples of medicines that can affect Co-Amilozide Tablets are:

- blood pressure lowering drugs (including angiotensin-converting enzymes (ACE) (eg. prazosin)

- medicines used to treat depression like lithium, reboxetine, tricyclic antidepressants and MAOIs
 - non-steroidal anti-inflammatory drugs (NSAIDs), such as Ibuprofen, Indometacin, used to treat pain or inflammation
 - other diuretics (water tablets)
 - Trilostane, used to treat problems of the adrenal gland
 - Cyclosporin and Tacrolimus, used to prevent rejection after organ transplants
 - barbiturates or narcotics which are used to induce sleep or to treat fits (epilepsy), like Carbamazepine
 - Cholestyramine and Colestipol, used to treat high blood cholesterol
 - Corticosteroids used to treat inflammatory conditions
 - Adrenaline used in the treatment of shock
 - Tubocurarine, used as muscle relaxants
 - Calcium or Potassium Salts used as dietary supplements
 - Antidepressants such as Paroxetine
 - medicines used to treat asthma
 - Carbamazepine (antiepileptic).
 - amphotericin and fluconazole used to treat fungal infections
 - quinidine, used to treat abnormal heart rhythms
 - carbenoxolone, used to treat stomach ulcers
 - medicines called muscle relaxants, such as tizanidine, used to treat muscle pain, spasms and twitching
 - medicine to treat Parkinson's disease (e.g. amantadine)
 - medicine to treat mental illness (e.g. primozide and sertindole)
 - medicines to treat diabetes eg. chlorpropamide
 - aprostadil used to treat impotence
 - cisplatin used to treat some cancers..
 - allopurinol used to prevent gout
 - hormones or drugs acting on hormones (e.g. trilostane, toremifene, oestrogens and progestrogens)
 - terfenadine, an anti-histamine used to treat allergies
 - cardiac glycosides medicines used in heart failure
 - barbiturate medicines used in sedation and anaesthesia.
- Tell your doctor if you are going into hospital for an operation.
- potassium, calcium and vitamin supplements.

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

Effects on laboratory tests

If you need to have any tests such as blood tests, urine tests, liver function, adrenal function or diabetes tests, tell the doctor that you are taking Co-Amilozide Tablets. You may need to stop taking the tablets before you take these tests.

Taking Co-Amilozide Tablets with food or alcohol

Drinking alcohol while taking these tablets may increase the risk of feeling faint on standing up. Do not eat foods which have a high potassium content (such as bananas). It is **important** to follow any dietary advice that you have been given by your doctor. If you are overweight, your doctor may want you to follow a weight reducing diet.

Driving and using machines

Co-Amilozide Tablets may cause drowsiness. You should not drive or operate machinery until the drug has been shown not to affect your physical or mental ability.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

If you have **diabetes**, Co-Amilozide Tablets may affect your blood sugar levels. Test your urine or blood regularly and report any extreme changes to your doctor.

Important information about some of the ingredients of Co-Amilozide Tablets

This medicinal product contains Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Also contains Sunset Yellow E110. May cause allergic reactions.

3. HOW TO TAKE CO-AMILOZIDE TABLETS

Always take Co-Amilozide Tablets exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure. Your doctor will have decided how many Co-Amilozide Tablets you need to take each day depending on your condition.

Swallow your tablets whole with a glass of water.

The rate of loss of weight and the serum electrolyte levels should determine the dosage. The most satisfactory rate of weight loss after initiation of diuresis is about 0.5 to 1.0 kg per day.

Adults: *Hypertension (high blood pressure):* The usual dose is one tablet (5/50mg) or two tablets (10/100mg) once a day or in divided doses. The dosage may be increased if necessary, but must not exceed four tablets (20/200mg) a day.

Congestive heart failure (Heart problems which can cause shortness of breath or ankle swelling): The usual dose is one tablet (5/50mg) or two tablets (10/100mg) a day to start, then adjusted if required, but not exceeding four tablets (20/200mg) per day. Your doctor will tell you how to take your tablets.

Hepatic cirrhosis with ascites (liver disorder): The usual dose is one tablet (5/50mg) a day, then adjusted if required, but not exceeding four tablets (20/200mg) per day. Your doctor may increase or decrease the dose depending on your response to the treatment.

Elderly: If you are elderly, the dose you take will be similar to the adults. Particular caution is needed in the elderly because of their susceptibility to electrolyte imbalance. Your doctor may adjust your dosage according to your kidney function and clinical response.

Children: Not recommended.

If you take more Co-Amilozide Tablets than you should

If you take more Co-Amilozide Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the pack and remaining tablets with you.

If you forget to take Co-Amilozide Tablets

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Co-Amilozide Tablets

Do not stop taking Co-Amilozide Tablets without talking to your doctor, even if you feel better. 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.

Very serious side effects – if any of the following happens, **stop taking** Co-Amilozide Tablets and tell your doctor immediately or go to the nearest hospital emergency department:

- rare allergic (Hypersensitive) reactions such as difficulty of breathing, swelling of your face, throat or tongue, skin rash, itching or nettle rash.

Very rarely, patients may experience:

- kidney problems
- heart problems
- inflammation of the pancreas
- swelling in the lungs
- worsening of diabetes
- severe pain and swelling in the joints
- brain disorders
- problems with the blood which can cause pale skin, sore throat or unexplained stomach or gut bleeding
- abnormal blood counts
- fits
- liver problems, including jaundice (skin or whites of the eyes turn yellow),
- coma in patients with liver disease
- itchy rash, which can be caused by exposure to sunlight.

The side-effects that some other patients have had with Co-Amilozide can be due to change in the levels of potassium and other salts in the blood. Symptoms can include:

- increase in the amount of water you pass
- headache
- feeling weak and tired, feeling irritable, dizzy, or faint particularly on standing up, vertigo, nausea
- loss of appetite
- feeling sick or being sick
- dehydration
- feeling drowsy or sleepy
- ringing in the ears
- confusion
- muscle cramps and weakness
- irregular or fast heartbeat
- reduction in the number of white blood cells (symptoms include frequent infections, fever, severe chills, sore throat or mouth ulcers)

Other side-effects;

- chest pains or back pain
- pain in legs or neck, pain in other parts of body
- diarrhoea or constipation, vomiting
- bloated feeling or hiccups
- stomach pains
- lack or loss of appetite
- high blood sugar (hyperglycaemia),
- dry mouth, feeling thirsty or bad taste in mouth
- nose blockage or cough
- sweating, fever
- Gout, a condition that causes pain, inflammation and swelling of your joints
- low blood platelet count (symptoms include bleeding or bruising more easily than normal. You may also notice purple or red-brown spots through the skin)
- pins and needles, loss of consciousness, nervousness, restlessness, sleeplessness, feeling depressed, difficulty or shortness in breathing, blurred vision, increased pressure in the eyes, seeing everything with a yellow tinge, impotence, reduced sexual desire, having to get up to pass water in the night, baldness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 TABLETS

Keep out of the sight and reach of children.

Do not store the tablets above 25°C. Keep them in the original pack. Do not take these tablets after the expiry date shown on the pack. 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.

6. FURTHER INFORMATION

What Co-Amilozide Tablets contain

The active substances are 5mg Amiloride Hydrochloride as the dihydrate and 50mg Hydrochlorothiazide. The other ingredients are Lactose Monohydrate, Calcium Hydrogen Phosphate, Maize Starch, Talc, Sodium Starch Glycollate, Magnesium Stearate and colour Sunset Yellow Lake (E110).

Sodium content per tablet: Maximum 0.3mg.

What Co-Amilozide Tablets look like and contents of the pack
Co-Amilozide Tablets are pale peach, flat bevelled edge tablets with 'RX' on one face, breakline and tablet code '237' on reverse.

Pack sizes: Container packs of 28, 100, 250, 500, 1000 tablets and blister packs of 28 and 30 tablets. Not all pack sizes may be marketed.

Manufacturer:

RX Farna Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom.

Marketing Authorisation Holder:

Special Concept Development (UK) Limited, Units 1-7 Colonial Way, Watford, Hertfordshire, WD24 4YR

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