8373

PACKAGE LEAFLET: INFORMATION FOR THE USER

CO-AMILOFRUSE TABLETS 5/40MG

(furosemide/anhydrous amiloride hydrochloride)

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT CO-AMILOFURSE TABLETS ARE AND WHAT THEY ARE USED FOR

Co-Amilofruse Tablets 5mg/40mg is the name of your medicine (called Co-Amilofruse Tablets throughout this leaflet). Co-Amilofruse Tablets contain two different medicines called: furosemide and amiloride hydrochloride. Both belong to a group of medicines called diuretics (water tablets).

- Heart failure
- Nephrosis (kidney disorder)
- Fluid retention due to steroids or oestrogen therapy
- Cirrhosis of the liver.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-AMILOFRUSE TABLETS

Do not take Co-Amilofruse Tablets if you

- Have ever had an allergic reaction to Co-Amilofruse Tablets, furosemide, amiloride, sulphonomides or sulphonamide derivatives or any of the ingredients in the tablet (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- Have reduced blood volume (hypovolaemia), are dehydrated or are not passing water (urine) due to a condition called anuria
- Have high levels of potassium in your blood, are taking potassium supplements or other potassium containing medicines. Or
- Have too much or too little potassium or sodium in your blood (shown in blood tests)
- Have severe kidney problems or kidney failure
- Have severe liver problems
- Have Addison's disease which is a disorder of the adrenal gland
- Are under 18 years of age
- Are breast-feeding (see Section Pregnancy and breast feeding).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking before taking Co-Amilofruse Tablets if you:

- Have a condition which affects your urination (passing water)
- Have low blood pressure
- Have reduced blood volume (hypovolaemia)
- Have gout (disease with painful, swollen joint caused by build up of uric acid crystals)
- Have low protein levels in the blood due to kidney problems
- Have cirrhosis of the liver together with kidney problems
- Have diabetes
- Are elderly with conditions such as low blood pressure, gout, kidney or liver problems
- Have conditions such as kidney problems affecting electrolyte deficiency in the blood (monitored with a blood test) (you may feel dizzy or dehydrate). Or where this medicine is taken in combination with certain other drugs which may lead to increased blood potassium levels
- Have been told by your doctor you have a rare hereditary sugar disease
- You are an elderly patient with dementia and are also taking risperidone
- Are going for a scan or X-ray using contrast material please tell the doctor you are taking Co-amilofruse
- Have systemic lupus erythematosus
- Are going to have a glucose tolerance test
- Have prostate problems.

Your doctor may want to monitor you whilst you take this medicine; this may mean having blood or urine tests or an ECG to check your heart.

Other medicines and Co-Amilofruse Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including the following:

- Medicines used to treat high blood pressure including aliskiren and anti-arrhythmics (irregular heart beat) such as disopyramide, flecainide, quinidine, amiodarone or sotalol
- Colestipol or colestyramine which are used to reduce cholesterol levels (fat)
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, aspirin and indometacin
- Phenytoin or carbamazepine which are used to treat epilepsy
- Methotrexate used to treat rheumatoid arthritis
- Probencid used to treat gout and kidney stones
- Sucralfate (do not take within two hours of co-amilofruse) or carbenoxolone used to treat stomach ulcers
- Medicines used to treat depression or behavioural problems such as lithium (as additional monitoring of patients on lithium may be required), amisulpride, atomoxetine, pimozide, sertindole or reboxetine
- Ciclosporin used to prevent organ rejection after transplant
- Anti-diabetics, medicines used to treat diabetes such as insulin and metformin
- Antibiotics and antifungals to treat infection including vancomycin, colistin and amphotericin
- Cisplatin used to treat various cancers
- Corticosteroids used in many conditions such as arthritis and asthma such as prednisolone
- Theophylline used to treat asthma
- Cardiac glycosides used to treat heart conditions e.g. digoxin
- Diuretics (“water tablets”) used to treat water retention
- Laxatives and liquorice preparations used to improve bowel movements (avoid prolonged use) such as bisacodyl or senna
- Medicines called ACE Inhibitors for treatment of heart problems e.g.captopril, or medicines called Angiotensin II receptor antagonists e.g. Losartan
- Resperidone used to treat schizophrenia, bipolar disorder, and irritability in people with autism
- Muscle relaxants (e.g. curare type relaxants)
- Medicines for infections such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins
- Medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- Aminoglutethimide used for breast cancer
- Medicines used as a general anesthetics for relaxing your muscle during surgery.

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

Pregnancy and breast-feeding

Pregnancy

Do not take Co-Amilofruse Tablets if you are pregnant.

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant. Your doctor will only prescribe Co-Amilofruse Tablets if the benefits to you outweigh the risks to the unborn child.

Breast-feeding

Do not breast-feed if you are taking Co-Amilofruse Tablets. This is because small amounts may pass into the mothers milk. Talk to your doctor before taking this medicine if you are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Co-Amilofruse Tablets may make you feel dizzy or confused. Make sure you are not affected before you drive or operate machinery.

Co-Amilofruse Tablets contain Sunset Yellow (E110)

This may cause allergic reactions.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. HOW TO TAKE CO-AMILOFRUSE TABLETS

Always take Co-Amilofruse Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Follow your doctor's instructions. Check the pharmacy label to see how many tablets to take and how often to take them. If you are still unsure ask your pharmacist or doctor.

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FRONT SIDE PRINTING

ARTWORK DETAIL LABEL

Product	**Co-Amilofruse Tablets - 5 / 40 mg**				
Buyer/Country	**Co-pharma**	Component	**Pack Insert**		
Dimension	**180 x 314mm**			Pack	---------
New Item Code	**1039667**	Old Item Code	1026849		
Colour Shades	**Black**			No. of Colours	**1**

Change Control No.	**PC-TSG/2019/280 - Record Number: 231193**	Artwork Version	**2.0**
Design/Style	**Front & Back Printing. To be supplied in the unfolded size.**		
Substrate	**60 GSM paper.**		
Special Instructions	**PRINTING CLARITY TO BE CLEAR & SHARP.**		
Autocartonator Requirements	**Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.**		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

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The usual dosage(s) are described below:

For Adult oral use

One or two tablets to be taken in the morning

Elderly

The above dosages may sometimes be reduced especially if you have damaged kidneys.

Elderly patients will have blood tests to closely monitor sodium, potassium and urea levels whilst on these tablets.

Children under 18 years of age

Not recommended.

Take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

If you take more Co-Amilofruse Tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Co-Amilofruse Tablets

If you forget to take a tablet take one as soon as you remember, unless it is nearly time to take the next one.

Do not take a double dose to make up for a forgotten dose.

Take the remaining doses at the correct time.

If you stop taking Co-Amilofruse Tablets

Keep taking this medicine until your doctor tells you to stop taking it.

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

4. POSSIBLE SIDE EFFECTS

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

Allergic reactions:

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you notice any of the following serious side effects you may need urgent medical treatment Frequency not known (cannot be estimated from the available data)

- Sudden wheeziness, difficulty in breathing, shortness of breath, fever, swelling of the eye lids, facelips tongue or other parts of the body, rash, itching or hives on the skin, (especially affecting your whole body)
- Sensitivity to light may occur
- Vasculitis (inflammation of the veins)
- Erythema multiforme (reddening of the skin)
- Exfoliative dermatitis (itchy red scaly skin)
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body
- Skin eruption with pustules and fever (Acute generalized exanthematous pustulosis) or skin rash accompanied with other symptoms such as fever and changes in the blood.

Serious side effects:

- Liver problems (yellowing of the skin or whites of the eyes), hepatic encephaolopathy (liver failure leading to confused state and coma)
- Reduction in the numbers of white blood cells and platelets (these can be detected by blood tests. These effects may result in unusual bruising or bleeding or increased risk of infection, fever, severe chills, sore throat or mouth ulcers)
- Anaemia (a condition in which there is a decrease in the number of red blood cells). Symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- Abnormal heart beats; this may be fast, slow or fluttering
- Pancreatitis (inflammation of the pancreas) this may show as severe stomach pain and nausea, weight loss and fat in the stools (foul smelling)
- Dehydration
- Hearing disorders or ringing in the ears (tinnitus), deafness.

If you experience any of the above side effects, contact your doctor immediately.

The following other side effects may also occur:

- Dizziness
- Feeling sick (nausea) or being sick (vomiting)
- Minor mental disturbances
- Glucose intolerance which may due to potential problems as a diabetic
- Diarrhoea or constipation
- Stomach pains
- Dry mouth
- Headaches or feeling of pressure in the head
- Lack of concentration
- Confusion
- Low blood pressure (reduced in reaction time and feeling light headed especially on standing)
- Inflammation of the blood vessels of the skin (purple spots or blisters on the skins surface)
- Rash which can be itchy, blood spots, bruising and discolouring to the skin (purpura)
- Muscle spasms or weakness
- General body weakness or feeling of being unwell
- Fever (high temperature)
- Increased urine production
- People with bladder and prostate problems may have pain when passing water.
- Urine retention (unable to pass urine), especially in patients who may already find it difficult to pass urine
- Changes in blood cell numbers measured by a blood test
- Increase in blood cholesterol levels
- Increase in blood creatinine and uric acid levels which may increase attacks of gout
- Reduction in blood calcium levels measured by a blood test
- Electrolyte imbalances in blood with symptoms of confusion, cramping, feeling sick, and muscle spasms
- Lichenoid reactions, characterized as small, itchy reddish purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- Systemic lupus erythematosus -symptoms vary considerably between patients but the most common are: joint aches and pains, swollen joints, headaches, increased sensitivity to sunlight, skin rashes, kidney problems, fatigue and weakness, mouth ulcers, hair loss, anxiety and depression, fevers and night sweats, abdominal pain, chest pain, shortness of breath, anaemia.

Blood tests

Co-amilofruse Tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides shown up on blood tests.

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-AMILOFRUSE TABLETS

Keep this medicine out of the sight and reach of children.

Store below 25°C. Protect from light.

Do not use this medicine after the expiry date which is stated on the label. The expiry refers to the last day of that month.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-Amilofruse Tablets contain

The active substances are furosemide and anhydrous amiloride hydrochloride.

The tablets also contain Mannitol, Pregelatinised maize starch, Povidone, Maize starch, Colloidal anhydrous silica (aerosil), Purified talc, Magnesium stearate and Sodium starch glycollate (explotab).

The film coating contains Opadry orange 8729 composed of: Hydroxypropylmethylcellulose 2910, Titanium dioxide (E171), Polyethylene glycol 400, Sunset yellow aluminium lake (E110), Quinoline yellow aluminium lake (E104), Purified water and Carnauba wax.

What Co-Amilofruse Tablets looks like and contents of the pack

Description:

Co-Amilofruse Tablets 5mg/40mg: A pale orange film coated tablet, marked CF with a breakline and 5/40 on one side and G on the reverse.

Contents of pack: Pots of 50, 100, 250 and 500 tablets or blisters of 28 or 56 tablets.

Marketing Authorisation Holder and Manufacturer

Co-Pharma
Unit 4, Metro Centre,
Tolpits Lane, Watford, Herts.
UK, WD18 9SS
Tel: 01923 255580
Fax: 01923 255581

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