PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-Amilofruse 2.5/20mg Tablets
Co-Amilofruse 5/40mg Tablets

amiloride hydrochloride and furosemide

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-Amilofruse Tablets are and what are they used for
2. What you need to know before you take Co-Amilofruse Tablets
3. How to take Co-Amilofruse Tablets
4. Possible side effects
5. How to store Co-Amilofruse Tablets
6. Contents of the pack and other information

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

Co-Amilofruse Tablets contain the active ingredients:
- furosemide, belonging to a group of medicines called loop diuretics which remove excess water but can cause a loss of potassium from the body.
- amiloride hydrochloride belongs to a group of medicines known as potassium sparing diuretics which also remove excess water but prevent excessive loss of potassium from the body.

Co-Amilofruse Tablets can be used to stop the build up of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual.

Co-Amilofruse Tablets work by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

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

Do not take Co-Amilofruse Tablets if you:
- have an allergy (hypersensitivity) to any of the ingredients in the product (*see Section 6 and end of Section 2*) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have severe problems with your kidneys
- have severe liver problems
- have a low blood volume or are dehydrated
- have too much or too little potassium or sodium in your blood (shown in blood tests)
- have an illness called 'Addison's disease'(underactive adrenal glands).This can make you feel tired and weak.
- are not passing any water (urine)
- are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- are breast-feeding (see “Pregnancy and breast-feeding” section below)
- taking other medicines which change the amount of potassium in your blood (see “Taking other medicines” section below)
- If the person taking the medicine is under 18 years. Co-amilofruse Tablets are not suitable for children

Do not take Co-Amilofruse Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-Amilofruse Tablets.

Warnings and precautions
Talk to your doctor or pharmacist before taking Co-Amilofruse Tablets if you:
- have difficulty in passing water (urine)
- have gout
- are 65 years of age or older
- have liver or kidney problems
- have diabetes
- have low blood pressure or feel dizzy when you stand up
- have prostate problems
- feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- are an elderly patient with dementia and are also taking risperidone
- are taking any other water tablets
- have systemic lupus erythematosus
- are going to have a glucose test
- are elderly, or you are on other medications which can cause the drop of the blood pressure and you have other medical conditions that are risks for the drop of blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co- Amilofruse Tablets.

Other medicines and Co-Amilofruse Tablets
Please tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines. This includes medicines you buy without a prescription including herbal medicines. This is because Co-Amilofruse Tablets can affect the way some other medicines work. Also, some medicines can affect the way Co-Amilofruse Tablets work.

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:
- Aliskiren – used to treat high blood pressure

Do not take this medicine, and tell your doctor, if you are taking:
- Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics) such as triamterene

The following medicines can affect the way Co-Amilofruse Tablets work and increase the chance of you getting side effects:
- Medicines such as ramipril, enalapril, perindopril (called 'ACE inhibitors') or losartan, candesartan, irbesartan (called 'angiotensin II receptor antagonists'). Your doctor may need to change the dose of your tablets or ask you to stop taking them
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine
- Medicines used as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are taking Co-Amilofruse Tablets.
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Co-Amilofruse Tablets

The following medicines can increase the chance of side effects when taken with Co-Amilofruse Tablets:
- Lithium - used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood.
- Cisplatin - used for some cancers
- Digoxin - used for heart problems. Your doctor may need to change the dose of your medicine.
- Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indometacin
- Carbamazepine - used for epilepsy
- Aminoglutethimide - used for breast cancer
- Ciclosporin - used to stop the rejection of organs after a transplant
- Methotrexate - used for cancers of the skin, joint or bowel diseases
- Carbenoxolone - used for ulcers of the food-pipe (gullet)
- Reboxetine - used for depression
- Amphotericin - used for fungal infections if used for a long time
- Corticosteroids - used for inflammation such as prednisolone
- Liquorice - often used in cough medicines if taken in large amounts
- Probenecid (used with another HIV medicine)
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins
- Medicines used as injections before X-ray examinations
- Medicines used for constipation (laxatives) if used for a long time such as bisacodyl or senna
- Medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- Other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine

Pregnancy and breast-feeding
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.

Do not breast-feed if you are taking Co-Amilofruse Tablets. This is because small amounts may pass into the mother's 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
You may feel dizzy or unwell after taking Co-Amilofruse Tablets. If this happens, do not drive or use any tools or machines.

Important information about ingredients of this medicine
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.
Sunset yellow FCF Lake- this colouring may cause allergic reactions.
Sodium - This medicine contains less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially 'sodium-free'.

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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.

The usual dose is one or two tablets first thing in the morning, swallowed with a glass of water. Your doctor will tell you how many tablets to take.

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

If you are taking sucralfate (a medicine for stomach ulcers)

Do not take sucralfate at the same time as Co-Amilofruse Tablets. Take your dose at least 2 hours before or after Co-Amilofruse Tablets. This is because it can affect the way your medicine works.

This medicine is not recommended for use in children.

If you take more Co-Amilofruse Tablets than you should
If you think you may have taken more Co-Amilofruse Tablets than you should, or if a child has swallowed any of your tablets, tell your doctor or go to your nearest hospital casualty department straight away. Remember to take with you any medicine that is left so the doctor knows what you have taken.

The following effects may happen: dry mouth, feeling thirsty, muscle pain or cramps, feeling sick or being sick (vomiting), weak or sleepy.

If you forget to take Co-Amilofruse Tablets
If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-Amilofruse Tablets

Keep taking Co-Amilofruse Tablets until your doctor tells you to stop taking it.

Blood tests
Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels.

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-Amilofruse Tablets can cause side effects, although not everybody gets them.

Tell a 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)

- If you have an allergic reaction. The signs may include inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Severe stomach or back pain. These could be signs of 'pancreatitis'
- Bruising more easily, getting more infections, feeling weak or tired more than usual. Co-Amilofruse Tablets can affect the number of blood cells, causing serious blood problems
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can also lead to blood clots or 'gout'
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.
- 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.
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption), symptoms include the skin becoming red with swollen areas covered in numerous small pustules
- Dizziness, fainting and loss of consciousness

Tell a doctor as soon as possible if you have any of the following side effects: Uncommon (may affect up to 1 in 100 people)

- Deafness (sometimes irreversible)

Frequency not known (cannot be estimated from the available data)

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Tingling or feeling numb on the skin
- Small changes in your mood such as feeling agitated or anxious.
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet
Frequency not known (cannot be estimated from the available data)

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.
- 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 (Systemic lupus erythematosus)
- Lichenoid reactions, characterized as small, itchy reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.

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.

Do not store above 25°C. Store in the original package and keep containers tightly closed. Do not use the tablets after the expiry date as stated on the label. 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-Amilofruse Tablets contains
The **active** substances are amiloride hydrochloride and furosemide.

The **other** ingredients are lactose monohydrate, microcrystalline cellulose, sunset yellow FCF lake (E110), povidone K30, sodium starch glycollate and magnesium stearate (*See Section 2 'Important information about some of the ingredients of Co-Amilofruse Tablets'*).

What Co-Amilofruse Tablets look like and contents of the pack
The Co-Amilofruse 2.5/20mg tablets are pale orange, circular and flat faced marked with ARD | 20 on one side and plain on the other side.
The Co-Amilofruse 5/40mg tablets are pale orange, circular and flat faced marked with ARD | 40 on one side and plain on the other side.

The product is available in white blister packs of 28, 30, 56 or 60 tablets as well as in container of 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

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