

PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-Amilorfruse 2.5mg/20mg Tablets

Co-Amilorfruse 5mg/40mg Tablets

Co-Amilorfruse 10mg/80mg 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, please 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-Amilorfruse Tablets are and what they are used for
2. What you need to know before you take Co-Amilorfruse Tablets
3. How to take Co-Amilorfruse Tablets
4. Possible side effects
5. How to store Co-Amilorfruse Tablets
6. Contents of the pack and other information

1. What Co-Amilorfruse Tablets are and what they are used for

The name of your medicine is Co-Amilorfruse Tablets. Co-Amilorfruse Tablets contain two different medicines called: furosemide and amiloride hydrochloride. Both belong to a group of medicines called diuretics (water tablets).

What Co-Amilorfruse Tablets are used for

Co-Amilorfruse 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.

How Co-Amilorfruse Tablets work

Co-Amilorfruse 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-Amilorfruse Tablets

Do not take Co-Amilorfruse Tablets if:

- You are allergic to furosemide, amiloride hydrochloride, sulphonamides (such as sulfadiazine or co-trimoxazole) or to any of the other ingredients of this medicine (listed in Section 6)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You have severe problems with your kidneys
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too much or too little potassium or sodium in your blood (shown in blood tests)
- You have an illness called 'Addison's Disease'. This can make you feel tired and weak
- You are breast-feeding (see "Pregnancy and breast-feeding" section below)
- You are taking other medicines which change the amount of potassium in your blood (see "Other medicines and Co-Amilorfruse Tablets" section below)
- If the person taking the medicine is under 18 years. Co-Amilorfruse Tablets are not suitable for children.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-Amilorfruse Tablets if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver or kidney problems
- You are an elderly patient with dementia and are also taking risperidone
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- You have prostate problems
- You have gout
- You 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
- You are going to have a glucose test
- You are taking any other water tablets
- You have systemic lupus erythematosus
- You 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-Amilorfruse Tablets.

Other medicines and Co-Amilorfruse Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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-Amilorfruse 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-Amilorfruse Tablets
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Co-Amilorfruse Tablets
- Colestyramine and colestipol - used for reducing cholesterol. Leave 2 to 3 hours apart, before and after taking Co-Amilorfruse Tablets.

The following medicines can increase the chance of side effects when taken with Co-Amilorfruse 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-Amilorfruse Tablets if you are pregnant. If you are pregnant or

breast-feeding, think you may be

pregnant or are planning a baby, ask your

doctor or pharmacist for advice before

taking this medicine.

Driving and using machines

You may feel dizzy or unwell after taking Co-Amilorfruse Tablets. If this happens, do not drive or use any tools or machines.

Co-Amilorfruse Tablets contain Sunset Yellow, Lactose and Sodium

This medicine contains:

- A colour called 'sunset yellow' (E110). This may cause allergic reactions.
- Lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine
- Sodium. This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Co-Amilorfruse Tablets

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

Your doctor will decide the right dose for you. This will be on the pharmacist's label. This medicine should be swallowed whole.

Adults

- The starting dose is usually 5mg/40mg taken in the morning; this can be adjusted by your doctor according to your response to treatment.

While you are taking this medicine 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.

Use in children

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

If you take more Co-Amilorfruse Tablets than you should

If you (or anybody else, including a child), takes more Co-Amilorfruse 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-Amilorfruse 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.

If you stop taking Co-Amilorfruse Tablets

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

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.

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-Amilorfruse 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).

Blood tests

Co-Amilorfruse 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-Amilorfruse Tablets

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

- Co-Amilorfruse Tablets should not be stored 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 label; the expiry date refers to the last day of the 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-Amilorfruse Tablets contains

The active ingredients are: amiloride hydrochloride and furosemide. The other ingredients are: lactose powder, microcrystalline cellulose, dispersed sunset yellow FCF Lake (E110), povidone K30, sodium starch glycolate, magnesium stearate, purified water.

Each Co-Amilorfruse 2.5mg/20mg tablet contains 2.84mg of amiloride hydrochloride equivalent to 2.5 mg of amiloride and 20mg of furosemide. Each Co-Amilorfruse 5mg/40mg tablet contains 5.68mg of amiloride hydrochloride equivalent to 5mg of amiloride and 40mg of furosemide. Each Co-Amilorfruse 10mg/80mg tablet contains 11.36mg of amiloride hydrochloride equivalent to 10mg of amiloride and 80mg of furosemide.

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

Co-Amilorfruse tablets are supplied in opaque white blister packs (containing 28, 30, 56 or 60 tablets) or in polyethylene plastic containers of 500 tablets.

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 formats:

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
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Co-Amilorfruse 2.5mg/20mg Tablets	PL 29831/0039
Co-Amilorfruse 5mg/40mg Tablets	PL 29831/0040
Co-Amilorfruse 10mg/80mg Tablets	PL 29831/0038

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

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