

Package leaflet: Information for the user

Fruco 40 mg/5 mg Tablets

Furosemide / 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 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.

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1. WHAT FRUCO TABLETS ARE AND WHAT THEY ARE USED FOR

Fruco 40 mg/5 mg Tablets contain furosemide and amiloride hydrochloride. Furosemide and amiloride hydrochloride belong to a group of medicines known as diuretics. Diuretics increase the amount of urine you produce by making your kidneys allow more water and salts to be removed from your body. Fruco Tablets are used to stop the build-up of extra water in your body.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FRUCO TABLETS

Do NOT take Fruco Tablets if you:

- are allergic to furosemide or amiloride hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have suffered from an allergic reaction to sulfonamides (medicines used to treat infections e.g. trimethoprim, sulfasalazine or sulfamethoxazole)
- suffer from Addison's disease (adrenal gland does not make enough corticosteroid)
- have been diagnosed as having high or low levels of potassium in your blood
- have low sodium levels in the blood
- have severe kidney problems
- have an abnormally low circulating blood volume
- have electrolyte imbalance
- in patients with pre-comatose and comatose states associated with disease of the brain caused by liver illness
- are taking potassium supplements (see section 2– **Other medicines and Fruco Tablets**)
- are dehydrated
- are pregnant or breast-feeding
- suffer from anuria (inability or difficulty urinating).

Fruco Tablets are NOT recommended for use in children.

Warnings and precautions

Talk to your doctor before you start to take this medicine if you:

- have a problem with your heart, such as heart failure, low or high blood pressure
- have diabetes. Taking Fruco Tablets may cause raised blood sugar levels (see section 4 – Possible side effects).
- have a blockage in your urinary tract, e.g. prostate enlargement in men (see section 4 – Possible side effects)
- have low levels of protein your blood (see Section 4 – Possible side effects)
- suffer from fast or irregular heart beats
- suffer from kidney or liver disease
- are taking risperidone (to treat some mental illnesses)
- are elderly, if you are on other medications which can cause the drop in the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure.

If you are at risk of developing fluid or electrolyte imbalance, your doctor may want to monitor you by performing blood tests while you are taking Fruco Tablets. If you suffer from dehydration, diarrhoea, vomiting, or severe sweating for more than a few days, **talk to your doctor**. You might need to stop taking Fruco Tablets (see section 4 – **Possible side effects**).

If you need to have a glucose tolerance test (to test for diabetes) whilst taking this medicine, please tell your doctor that you are taking Fruco Tablets. You will need to stop taking the tablets for a while before the test.

Other medicines and Fruco Tablets

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

Do NOT take Fruco Tablets if you are taking:

- potassium supplements or any medicine containing potassium.

Talk to your doctor if you are taking any of the following:

- other diuretics e.g. spironolactone or triamterene
- aminoglycoside antibiotics e.g. gentamycin
- cephalosporin antibiotics e.g. cefatrizine or cefaclor
- chloral hydrate (to treat insomnia or pain control)
- lithium (to treat mental illness)
- sucralfate (to treat duodenal ulcers); do not take sucralfate at the same time as Fruco Tablets. Take your dose at least 2 hours before or after Fruco Tablets. This is because it can affect the way your medicine works.
- heart medicines or medicines to lower your blood pressure, especially ACE inhibitors e.g. captopril, and angiotensin II receptor antagonists e.g. telmisartan and losartan
- non-steroidal anti-inflammatory agents (NSAIDs) e.g. indomethacin or aspirin, also known as acetylsalicylic acid (to treat pain and swelling)
- corticosteroids or carbenoxolone (to treat inflammation)
- laxatives
- liquorice in large amounts
- digoxin (to treat heart problems)
- phenytoin (to treat epilepsy)
- theophylline (to treat bronchospasm)
- cyclosporine (to prevent rejection of organ transplant)
- probenecid (to treat gout)
- have been given cisplatin or methotrexate (to treat cancer)
- anti-diabetic medicines e.g. glimepiride or metformin
- risperidone (to treat some mental illnesses)
- muscle relaxants
- have received a radiocontrast agent during treatment of a kidney disease.

If you are going to have an operation, please tell the

anaesthetist that you are taking Fruco Tablets as this may affect some of the medicines they may use. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Fruco Tablets with food and drink

Fruco Tablets should be taken with a sufficient amount of liquid. This medicine is best taken on an empty stomach.

Pregnancy and breast-feeding

You **MUST NOT** take Fruco Tablets if you are pregnant or breast-feeding. If you are pregnant or planning to become pregnant you **MUST** tell your doctor.

Driving and using machines

Fruco Tablets may make you feel less alert than usual.

This applies especially at the commencement of treatment or after consumption of alcohol. If affected, do **NOT** drive or operate machinery.

Fruco Tablets contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Fruco Tablets contain **sunset yellow dye E110**. It may cause allergic reactions.

3. HOW TO TAKE FRUCO TABLETS

Always take Fruco Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Fruco Tablets should be swallowed whole, preferably with a drink of water. They are best taken on an empty stomach. The recommended dose is:

- **Adults**

One tablet in the morning (may be increased to two tablets, preferably taken in two doses, one to be taken in the morning and the other at noon).

- **Elderly patients**

Your doctor may alter the dose you take depending on your response to Fruco Tablets.

- **Children**

Fruco Tablets are **NOT** recommended for use in children.

If you take more Fruco Tablets than you should

If you (or someone else) swallowed a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor **immediately**. An overdose is likely to cause dehydration. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were taken.

If you forget to take Fruco Tablets

If you forget to take a Fruco 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. If it is almost time to take the next dose, wait until then and then carry on as before.

If you stop taking Fruco Tablets

Do **NOT** stop taking your medicine without talking to your doctor first 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, Fruco Tablets can cause side effects, although not everybody gets them.

If the following happens, **STOP** taking Fruco Tablets and tell your doctor **immediately** or go to the casualty department at your nearest hospital:

- **sudden life-threatening allergic reaction** (anaphylaxis) with sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- abnormally high level of uric acid in your blood (hyperuricaemia) and **painful, swollen joints** caused by uric acid crystals (gout)
- **inflammation of the pancreas** (pancreatitis) which may cause severe pains in your abdomen or back, nausea, vomiting, and fever
- sudden **inability or difficulty urinating**
- skin eruption with sudden appearance of red areas with small blisters, filled with fluid; increased skin sensitivity to touch and light, skin prickling.

These are very serious, but rare side effects. You may need urgent medical attention or hospitalisation.

Some effects may occur due to other pre-existing conditions (see section 2 - **Warnings and precautions**):

Common side effects (may affect up to 1 in 10 people)

- if you have ever had problems passing urine, or you have an enlarged prostate, you may experience a build-up of urine

Rare side effects (may affect up to 1 in 1000 people)

- if you have a tendency to high levels of blood sugar, diabetes may develop.

If you experience these effects or are worried about them, talk to your doctor.

If you suffer from any of the following for more than a few days, tell your doctor:

Rare side effects (may affect up to 1 in 1000 people)

- dehydration, increased thirst, headache, cramps, low blood pressure (which may make you sweat, feel light-headed or faint), stomach upset, diarrhoea, constipation, feeling or being sick, or a general feeling of being unwell. You might need to stop taking this medicine.

You may need to have blood tests to find out if you have any of the following side effects:

Common side effects (may affect up to 1 in 10 people)

- increased potassium levels
- increased uric acid levels, possibly causing gout

Rare side effects (may affect up to 1 in 1000 people)

- increased cholesterol or triglyceride levels, which usually return to normal within 6 months during long term therapy
- abnormally low circulating blood volume
- decreased calcium levels, in very rare cases cramps may occur to the hand, feet or face
- change in the acid/base balance of the body

Very rare side effects (may affect up to 1 in 10,000 people)

- decrease in red or white blood cells or platelets
- liver problems.

The following side effects have been reported:

Common side effects (may affect up to 1 in 10 people)

- blood clots
- narrowing or blockage of blood vessels
- kidney problems
- disease with painful, swollen joints caused by uric acid crystals (gout)

Uncommon side effects (may affect up to 1 in 100 people)

- allergic reactions of the skin with rash, itching, hives, blisters, discoloration or photosensitivity reactions
- bleeding or bruising more easily than normal
- deafness (sometimes irreversible)

Rare side effects (may affect up to 1 in 1000 people)

- frequent infections with fever, severe chills, sore throat or mouth ulcers
- hearing disorders, ringing in the ears and damage to the inner ear, which can affect your hearing or balance
- low blood pressure
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- impaired concentration and reactions
- sensations of pressure in the head
- feeling sick
- being sick
- diarrhoea
- headache
- sleepiness
- feelings of weakness
- disorders of vision
- increased rate of breathing
- dryness of the mouth
- tingling or numbness of the hands or feet
- mental disturbances

Very rare side effects (may affect up to 1 in 10,000 people)

- inflammation of the pancreas
- liver and bile duct problems
- reduction in red blood cells which can make the skin pale or yellow and cause weakness or breathlessness

Not known (cannot be estimated from the available data)

- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

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

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FRUCO TABLETS

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

You should keep your tablets in a dry place, below 25°C and away from light. Keep them in the pack they came in. Do not put them into another container.

Do not use Fruco Tablets after the expiry date that is stated on the outer packaging. The expiry date 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 Fruco Tablets contain:

- The active ingredients are furosemide 40 mg and amiloride hydrochloride 5 mg.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, croscarmellose sodium, magnesium stearate, talc and sunset yellow (E110).

What Fruco Tablets look like and contents of the pack:

Fruco Tablets are round orange flat, beveled tablets, coded 'Fruco' with a breakline on one face, plain on the reverse.

Fruco Tablets come in packs of 28 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Norton Healthcare Ltd. T/A IVAX Pharmaceuticals UK, Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX, United Kingdom

Company responsible for manufacture: Teva Pharmaceutical Works Private Limited Company, Táncsics Mihály út 82, H-2100 Gödöllő, Hungary

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