

Package Leaflet: Information for the user
Fruside 40 mg Tablets
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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

Fruside tablets contain the active ingredient furosemide, which belongs to a group of medicines known as diuretics (water tablets). These medicines are used to treat fluid retention and oedema, in which your body has retained too much water due to mild to moderately high blood pressure or problems with your heart, lungs, kidneys or liver. Fruside tablets increase the amount of urine produced.

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

Do NOT take Fruside tablets:

- if you are allergic to furosemide or 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
- if you are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- if you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide
- if you have severe liver problems
- if your doctor has told you that you have low blood volume or are dehydrated
- if you are not passing water (urine)
- if you have too little potassium or sodium in your blood (shown in blood tests)
- if you are breast-feeding (see “pregnancy and breast-feeding” section below).

Do not use Fruside tablets if any of the above apply to you. If you are not sure, talk to your doctor or nurse before taking Fruside tablets.

Warnings and precautions

Talk to your doctor before taking Fruside tablets:

- if you have difficulty in passing water (urine)
- if you are 65 years of age or older
- if you are taking an antipsychotic drug called risperidone
- if you have low levels of protein in your blood (hypoproteinemia). This will show in your blood tests
- if you suffer from acute porphyria symptoms of which may include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also present along with weakness in arms and legs
- if you have liver or kidney problems
- if you have diabetes
- if you have low blood pressure or feel dizzy when you stand up
- if you have prostate problems
- if you have gout
- if 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
- if you are going to have a glucose test
- if the person taking the medicine is a premature infant. This is due to the possible formation of kidney stones
- if you have systemic lupus erythematosus (SLE) – a disease of the immune system which affects skin, bones, joints and internal organs
- if you are elderly, if you are on other medications which can cause a drop in blood pressure and if 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 nurse before taking Fruside tablets.

Other medicines and Fruside tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking any of the following:

The following medicines can affect the way Fruside tablets work and increase the chance of you getting side effects:

- medicines such a 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 to help you sleep and relax such as chloral hydrate
- 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 Fruside tablets
- theophylline – used for wheezing or difficulty in breathing
- phenytoin – used for epilepsy. This can lower the effect of Fruside tablets
- risperidone – an antipsychotic drug.

The following medicines can increase the chance of side effects when taken with Fruside 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 indomethacin
- carbamazepine – used for epilepsy
- aminoglutethimide – used for breast cancer
- ciclosporin – used to stop the rejection of organs after transplant
- methotrexate – used for cancers of the skin, joint or bowel diseases
- carbenoxolone and sucralfate – used for ulcers of the food pipe (gullet)
- reboxetine – used for depression
- amphotericin – used for fungal injections 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 before X-ray examinations (radiocontrast agents)
- 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 and metolazone
- medicines used for thyroid problems such as levothyroxine.

Your doctor may need to change the dose of your medicine.

Pregnancy and breast-feeding

Do **not** take Fruside tablets if you are pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not breast-feed if you are taking Fruside tablets. This is because small amounts may pass into the mother’s milk. 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 having Fruside tablets. If this happens, do not drive or use any tools or machines.

Fruside tablets contain lactose

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

3. HOW TO TAKE FRUSIDE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablet whole with a drink of water.

The recommended doses are:

Adults

The starting dose is 1 tablet once a day. This may be adjusted to suit your needs, which may be half a tablet on alternate days up to 3 tablets daily.

Elderly patients

Your dose will be adjusted gradually until the required response is seen. Your doctor will advise you.

Children

The usual dose is 1-3 mg per kg of bodyweight.

If you take more Fruside tablets than you should

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you. Having too many Fruside tablets may make you feel confused, unable to focus, show a lack of emotion or interest in anything. You may also have dizziness, lightheadedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of body that is affected). You may also have problems with your kidneys or blood.

If you forget to take Fruside tablets

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining doses at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fruside tablets

Keep taking your tablets for as long as your doctor has told you to. Do not stop taking these tablets without asking your doctor first.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- if you have an allergic reaction. The signs may include a rash, joint pain, fever (systemic lupus erythematosus), 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
- you bruise more easily, get more infections, feel weak or tired more than usual. Fruside tablets can affect the number of blood cells, causing serious blood problems.

Very common (affects more than 1 in 10 people):

- 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 lead to blood clots or ‘gout’.

Common (affects less than 1 in 10 people):

- 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.

Rare (affects less than 1 in 1,000 people):

- severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- inflammation of your blood vessels (vasculitis). Symptoms may include fever, loss of appetite, weight loss, aches and pains.

Very rare (affects less than 1 in 10,000 people):

- severe stomach or back pain. These could be signs of ‘pancreatitis’.

Frequency unknown:

- you find it hard to urinate. This could be a symptom of acute urinary retention
- you suffer from a kidney disorder where there is an increased amount of calcium in your kidneys. This could be a symptom of nephrocalcinosis
- you suffer from blood in your urine or pain in your abdomen or groin. This could be a sign of kidney stones (nephrolithiasis)
- 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
- you have blood clots
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- you have muscle weakness, tenderness or pain. You may also feel unwell or have a high temperature. You may have something called “rhabdomyolysis”. This is a rare but serious illness that may be life-threatening.

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people):

- 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
- change in the amount of some salts (such as calcium, potassium, magnesium, sodium and chloride) which are needed for your body to work properly. Signs include increased thirst, headaches, low blood pressure, confusion, muscle cramps, muscle weakness, fast or irregular heart rate and stomach upset.

Uncommon (affects less than 1 in 100 people):

- problems hearing
- deafness (sometimes irreversible).

Rare (affects less than 1 in 100 people):

- tingling or feeling numb on the skin.

Very rare (affects less than 1 in 10,000 people):

- ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- reduction in blood cells which can cause bruising, make infections more likely, make skin pale yellow or cause weakness or breathlessness (anaemia).

Frequency unknown:

- change in the levels of some salts (such as sodium or chloride) in the urine
- dizziness, fainting or loss of consciousness caused by symptomatic hypotension or by other causes), headache.

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

Common (affects less than 1 in 10 people):

- passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

Uncommon (affects less than 1 in 100 people):

- feeling sick (nausea) or a general feeling of being unwell
- if you have diabetes you may be less able to control the levels of glucose in your blood.

Rare (affects less than 1 in 1,000 people):

- diarrhoea and being sick (vomiting).

Very rare (affects less than 1 in 10,000 people):

- an illness where the removal of bile from the liver is blocked (intrahepatic cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker.

Frequency unknown:

- people with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- pain at the site of injection. This occurs when the medicine is injected into the muscle.

Blood tests

Fruside tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides. A blood test may show changes in the way the kidneys are working, indicating a significant reduction in kidney function.

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 FRUSIDE TABLETS

Keep out of the sight and reach of children. Do not store above 25°C. Do not use the tablets after the expiry date which is 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

Fruside tablets contain:

- the **active** ingredient is furosemide (40 mg per tablet)
- the **other** ingredients are lactose monohydrate (*see also end of Section 2 for further information on lactose*), maize starch, microcrystalline cellulose (E460), sodium starch glycollate (Type A), talc (E553b), colloidal anhydrous silica and magnesium stearate.

What Fruside tablets look like and contents of the pack

Fruside 40 mg tablets are white, flat with a bevel-edge engraved with “2B2” on one side and a breakline on the other side. The tablets are provided in plastic containers with plastic caps or child resistant closures in packs of 30, 50, 100, 500, 1000 or 5000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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