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**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Frumil® 40mg/5mg Tablets

Furosemide 40mg

Amiloride Hydrochloride 5mg

SANOFI



Is this leaflet hard to see or read?

Phone 0800 035 2525 for help

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

1. What Frumil Tablets are and what they are used for



What Frumil Tablets are

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

What Frumil Tablets are used for

Frumil 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 Frumil Tablets work

Frumil 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 Frumil Tablets



Do not take Frumil Tablets if:

- × You are allergic (hypersensitive) to furosemide, amiloride hydrochloride 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
- × You are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- × 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 "Taking other medicines" section below)
- × If the person taking the medicine is under 18 years. Frumil Tablets are not suitable for children

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

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Warnings and precautions

Talk to your doctor or pharmacist before taking Frumil 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 Frumil Tablets.

Turn
Over



Other medicines and Frumil 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 Frumil Tablets can affect the way some other medicines work. Also, some medicines can affect the way Frumil Tablets work.

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 Frumil 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 Frumil Tablets.
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Frumil Tablets

The following medicines can increase the chance of side effects when taken with Frumil 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 Frumil 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 Frumil 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

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

Frumil Tablets contain Sunset Yellow and Lactose

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

3. How to take Frumil Tablets

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much Frumil Tablets to take

The usual dose is one or two tablets first thing in the morning. Your doctor will tell you how many tablets to take.

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

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

If you take more Frumil Tablets than you should

If you think you may have taken more Frumil Tablets than you should, or if a child has swallowed any of your tablets, tell your doctor or got 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 uneven heartbeat, feeling dizzy, weak or sleepy.

If you forget to take Frumil Tablets

If you forget a dose, take it as soon as you remember it. Then continue the following morning as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Frumil Tablets

Keep taking Frumil 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, 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. Frumil 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

Frumil 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.

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5. How to store Frumil Tablets

- Keep this medicine out of the sight and reach of children.
- Do not take Frumil Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Store below 25°C. Keep the blister strip in the outer carton in order to protect from light and moisture.

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 Frumil Tablets contain

One of the active ingredients in this medicine is furosemide 40mg. This is the new name for frusemide 40mg. The ingredient itself has not changed

- The active substances are furosemide and amiloride hydrochloride. Each tablet contains 40mg furosemide and 5mg amiloride hydrochloride (as anhydrous)
- The other ingredients are lactose, maize starch, microcrystalline cellulose, sodium starch glycollate, talc, sunset yellow dye (E110), colloidal anhydrous silica and magnesium stearate

What Frumil Tablets look like and contents of the pack

Frumil Tablets are orange, evenly mottled circular tablets with bevel edges and 'FRUMIL' embossed on one side, with a breakline on the other side.

Your tablets are available in blister packs of 4, 7, 28, 56 and 1400 tablets or bottles containing 50, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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