

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Frumil® 40mg/5mg Tablets***Furosemide*

#### *Amiloride Hydrochloride*

Is this leaflet hard to see or read?

Phone 01 403 5600 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 works 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 vessel, lungs, kidneys or liver.

### **2. What you need to know before you take Frumil Tablets**

#### **Do not take Frumil Tablets:**

- You are allergic (hypersensitive) to furosemide, amiloride hydrochloride or any of the other ingredients of Frumil Tablets (listed in Section 6 below). 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 cotrimoxazole.
- 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 Frumil Tablets" section below).
- If the person taking the medicine is under 18 years. Frumil is 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.

### **Warnings and Precautions**

#### **Talk to your doctor or pharmacist before taking your medicine if:**

- You have difficulty in passing water (urine)
- You are elderly (over 65 years of age)
- You are taking an antipsychotic drug called risperidone
- You have liver or kidney problems
- 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 have systemic lupus erythematosus (a disease of the immune system which affects skin, bones, joints and internal organs).
- You are taking any other water tablets
- 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 pharmacist before taking Frumil Tablets.

#### **Other medicines and Frumil Tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken 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. And, 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.

**Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:**

- **A**aliskiren - used to treat high blood pressure.

**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 Frumil 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 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 foodpipe (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, breast-feeding and fertility**

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 contains:**

This medicine contains:

A colour called 'sunset yellow E110'. This may cause allergic reactions -including asthma. Allergy is more common in people who are allergic to aspirin.

Lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine

### **Frumil contains Sodium**

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially "sodium free".

## **3. How to take Frumil Tablets**

Always take Frumil Tablets exactly as your doctor has told you. You should 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 to take**

The usual dose is one tablet to be taken in the morning. This may be increased to two tablets. If taking two tablets take one in the morning and one at noon. 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 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 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 level of some salts in the blood are at the correct level.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, Frumil 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**

- 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
- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption) frequency not known
- Side effect with frequency not known: Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- 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
- Decrease in urine output, swelling in your legs, ankles and feet caused by retention of fluid, unexplained shortness of breath, excessive drowsiness or fatigue - these could be signs of renal failure
- 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.

- 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 a doctor as soon as possible if you have any of the following side effects:**

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys.
- deafness (sometimes irreversible) frequency: uncommon (affects less than 1 in 100 people)
- 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
- Dizziness, fainting or loss of consciousness, headache - frequency not known

**Tell a 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**

- 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 level of glucose in your blood.
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

**Blood tests**

Frumil Tablets can change the level of liver enzymes or body fats such as cholesterol and triglycerides shown up on blood tests.

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, Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Frumil Tablets**

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package in order to protect from light.

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

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**

Frumil Tablets contain two active substances furosemide and Amiloride Hydrochloride.

Frumil 40mg/5mg tablets contain 40mg of furosemide and 5mg of amiloride hydrochloride.

The other ingredients are lactose monohydrate, 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 40mg/5mg Tablets are orange, circular, uncoated tablets with a breakline on one side and 'FRUMIL' on the reverse.

Your tablets are available in blister packs of 28 and 56 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

sanofi-aventis Ireland Ltd., T/A SANOFI  
Citywest Business Campus  
Dublin 24  
Tel: 01 403 5600  
Fax: 01 403 5687  
Email: IEmedinfo@sanofi.com

#### **Manufacturer**

Sanofi S.r.l.  
Strada Statale 17, Km 22,  
67019 Scoppito (L'Aquila),  
Italy.

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.

This leaflet was last revised in ~~January~~ February 2024<sup>43</sup>.