

Frumil®

Furosemide (frusemide) 40mg/amiloride hydrochloride 5mg

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Frumil.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Frumil is used for

Frumil contains a combination of two diuretics, furosemide (frusemide) and amiloride as the active ingredients. A diuretic helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

Frumil is used for the treatment of heart failure. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may

wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

The combination of active ingredients in Frumil work by making your kidneys pass more water and salt whilst minimising potassium loss.

Frumil may be taken alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed Frumil for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take Frumil if you have:

- **certain kidney problems**
- **low sodium levels in your blood**
- **low potassium levels in your blood**
- **you are taking potassium supplements**
- **high potassium levels**
- **dehydration**

Do not take Frumil if you are allergic to:

- **this medicine or any of the ingredients listed at the end of this leaflet**

- **medicines called sulfonamides (eg. some types of antibiotics which are also referred to as 'sulfur antibiotics') or sulfonylureas which are medicines which can be used to treat diabetes**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take Frumil if you are pregnant or intend to become pregnant.

Like most diuretic medicines, Frumil is not recommended for use during pregnancy.

Do not take Frumil if you are breast-feeding or planning to breast-feed.

The active drug, furosemide (frusemide), passes into breast milk and there is a possibility your baby may be affected. It is not known whether amiloride passes into the breast milk. Frumil is not recommended for use during breast feeding.

Do not give Frumil to children.

The safety of Frumil in children has not been established.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Frumil if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines called sulfonamides or sulfonyleureas
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Frumil is not recommended to be used during pregnancy. If there is a need to consider Frumil during your pregnancy, your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Frumil passes into breast milk and there is a possibility your baby may be affected. Your doctor will discuss the risks and benefits of taking it if you are breast-feeding or planning to breast-feed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- diabetes
- gout, a disease with painful, swollen joints
- high potassium levels in the blood
- no production or no passing of urine
- prostate problems

Tell your doctor if you are on a salt restricted diet.

Tell your doctor if you are following a potassium-rich diet (i.e. eating foods which are high in potassium such as bananas or oranges) or are taking potassium supplements.

Your blood potassium levels may increase too much.

If you have not told your doctor about any of the above, tell them before you take Frumil.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines should not be taken with Frumil. This includes large amounts of laxatives.

Some medicines may interfere with Frumil. These include:

- certain other fluid tablets or diuretic medicines
- tablets or supplements containing potassium (e.g. Slow-K, Span-K, KSR)
- medicines used to treat high blood pressure and some other heart conditions, especially ACE inhibitors or angiotensin receptor antagonists
- digoxin and other medicines used to treat heart failure
- non-steroidal anti-inflammatory drugs (NSAIDs) and aspirin, medicines used to relieve pain
- medicines used to relax muscles before or during surgery
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used in emergency situations such as adrenaline (epinephrine) and noradrenaline (norepinephrine)
- ciclosporin and medicines used in organ transplant
- cisplatin, a medicine used to treat cancer
- theophylline, a medicine used to treat asthma
- certain antibiotics, especially cephalosporins and aminoglycosides
- insulin and tablets used to treat diabetes

- sucralfate, a medicine used to treat stomach ulcers
- phenytoin, a medicine used to treat epilepsy
- risperidone, a medicine used to treat mental illnesses
- methotrexate, a medicine used to treat arthritis and some types of cancer
- probenecid, a medicine used to treat gout
- corticosteroids such as cortisone, prednisone or dexamethasone
- medicines used to treat thyroid conditions
- medicines used during scans to see the images of your body

These medicines may be affected by Frumil, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

You should not eat large amounts of liquorice when you are taking Frumil.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Frumil.

How to take it

How much to take

Follow the directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you. If you take the wrong dose, Frumil may not work as well and your problem may not improve.

How to take it

Take Frumil tablets with a glass of water. Frumil is best taken on an empty stomach.

When to take it

Frumil tablets are usually taken once a day in the morning.

Take Frumil tablets on an empty stomach. For example, one hour before food or two hours after food.

Food can interfere with their absorption.

Take Frumil tablets at about the same time each day unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

If your doctor prescribes Frumil tablets to be taken once a day, it is best done in the morning, for example, before breakfast.

If you are taking Frumil tablets more than once a day, take your first dose immediately before breakfast and take your last dose around 12 noon (on an empty stomach), unless your doctor tells you otherwise.

Frumil may increase the amount of urine you pass, it will also increase the number of times you need to go to the toilet. By taking your last dose around 12 noon, there may be less chance that your sleep is disturbed.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

The medicine helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre 0800 POISON or 0800 764766, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Frumil.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Frumil, you may feel confused, dehydrated, dizzy or you may pass excessive urine.

You may also vomit, have muscle cramps or an irregular heart beat.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Frumil.

If you are about to be started on any new medicine, tell your doctor

and pharmacist that you are taking Frumil.

If you plan to have a surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Make sure you drink enough water during any exercise and during hot weather when you are taking Frumil, especially if you sweat a lot.

If you do not drink enough water while taking Frumil, you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly and you are dehydrating. If you continue to feel unwell, tell your doctor.

If you are about to have any blood tests, tell your doctor that you are taking Frumil.

There may be some interference with the results of these tests.

Keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Frumil, or change the dosage, without checking with your doctor.

Things to be careful of

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy when you begin to take Frumil. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from beds or chairs, will help your body

get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful driving or operating machinery until you know how Frumil affects you.

Diuretic medicines may cause dizziness or light-headedness in some people. Make sure you know how you react to your medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

If this occurs do not drive.

If you drink alcohol or take strong painkillers, dizziness or light-headedness may be worse.

Be aware of foods, drinks or supplements that have a high potassium content.

Frumil helps to maintain a normal potassium level in your body. However, if you eat foods or have drinks that are high in potassium this may lead to an increase of potassium in your body, which can be harmful. Your doctor and pharmacist have more information on potassium-rich foods.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Frumil.

Frumil helps most people with heart failure, but it may have unwanted side effects in a few people.

Tell your doctor if you notice any of the following and they worry you:

- very dry mouth or unusual thirst
- muscle pains or cramps
- dizziness or light-headedness
- fever
- vomiting or nausea, loss of appetite
- diarrhoea
- ringing or buzzing in the ears

These are more common side effects of Frumil. Mostly they are mild or short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- irregular or fast heart beat
- passing less urine than is normal for you
- pain when passing urine
- severe dizziness or a spinning sensation
- flaking or peeling of the skin
- symptoms of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- loss of control of your bladder or bowels (incontinence)
- gout, a disease with painful, swollen joints
- deafness or ringing in the ears

These may be serious side effects of Frumil. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives (pinkish, itchy raised areas) on the skin, swelling of the face, lips, tongue

or other parts of the body, shortness of breath, wheezing or trouble breathing

- chest pain or a feeling of tightness in the chest
- fainting or having a rapid, weak pulse
- an irregular heart beat or palpitations
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black, sticky bowel motions (stools) or bloody diarrhoea
- red, often itchy spots similar to the rash seen with measles which starts on the limbs and sometimes on the face and body. The spots may blister and may progress to form raised red, pale-centred marks. Those affected may have fever, sore throat, headache with or without diarrhoea
- yellowing of the skin and/or eyes (jaundice)

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your Frumil tablets in the blister pack until it is time to take them.

If you store your Frumil tablets out of the container they may not keep well.

Keep your Frumil tablets in a cool dry place where the temperature stays below 25°C.

Do not store Frumil or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Frumil or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Manufacturer/Sponsor

Frumil is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 8, 56 Cawley Street

Ellerslie, Auckland

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Product description

What it looks like

Frumil tablets are orange, scored with FRUMIL on reverse side.

Ingredients

Active ingredient:

Frumil tablets contain furosemide (frusemide) 40mg and amiloride 5mg

Inactive ingredients:

Frumil tablets also contain lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycollate, silicon dioxide, purified talc, magnesium stearate, sunset yellow FCF.