

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Frumil?

Frumil contains the active ingredients furosemide and amiloride. Frumil is a diuretic used for the treatment of heart failure. It is used to help reduce the amount of excess fluid in the body by increasing the amount of urine produced.

For more information, see Section [1. Why am I using Frumil?](#) in the full CMI.

2. What should I know before I use Frumil?

Do not use if you have ever had an allergic reaction to furosemide, amiloride, sulfonamides (e.g. 'sulfur antibiotics'), sulfonyleureas or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Frumil?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Frumil and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Frumil?

Frumil tablets should be taken in the morning with a glass of water on an empty stomach, that is one hour before food or two hours after food. If you are taking Frumil more than once a day the second dose should be around 12 noon.

More instructions can be found in Section [4. How do I use Frumil?](#) in the full CMI.

5. What should I know while using Frumil?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Frumil.Make sure you drink enough water during any exercise and during hot weather when you are taking Frumil, especially if you sweat a lot.Tell your doctor straight away if you become pregnant or intend to become pregnant.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">Frumil may cause dizziness or light-headedness in some people. If this happens, do not drive or operate machines.
Drinking alcohol	<ul style="list-style-type: none">If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">Keep your Frumil tablets in the blister pack until it is time to take them.Keep your Frumil tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Frumil?](#) in the full CMI.

6. Are there any side effects?

Very serious side effects may include 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, chest pain, yellowing of the skin or eyes (jaundice), fainting or a rapid, weak pulse. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Frumil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Frumil.**

Where to find information in this leaflet:

1. [Why am I using Frumil?](#)
2. [What should I know before I use Frumil?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Frumil?](#)
5. [What should I know while using Frumil?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Frumil?

Frumil contains the active ingredients furosemide and amiloride hydrochloride. Frumil is a combination of two diuretics. 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

2. What should I know before I use Frumil?

Warnings

Do not use Frumil if you:

- are allergic to furosemide, amiloride, sulfonamides (e.g. 'sulfur antibiotics'), sulfonyleureas or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- have certain kidney problems
- have low sodium levels in your blood
- have low potassium levels in your blood
- are taking potassium supplements
- have high potassium levels
- are dehydrated
- have allergies to any other substances, such as foods, preservatives or dyes.

Check with your doctor if you have:

- 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
- take any medicines for any other condition

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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. If there is need to consider Frumil during your pregnancy, your doctor will discuss the risks and benefits of taking it if you are pregnant.

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. Your doctor will discuss the risks and

benefits of taking it if you are breast-feeding or planning to breast-feed.

Use in Children

Do not give Frumil to children. The safety of Frumil in children has not been established.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Frumil and affect how it works.

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
- large amounts of laxatives
- large amounts of liquorice

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Frumil.

4. How do I use Frumil?

How much to take

- The usual initial adult dose is one tablet in the morning with a glass of water on an empty stomach.
- **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.
- Follow the instructions provided and use Frumil until your doctor tells you to stop. The medicine helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

When to take Frumil

- 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.

If you forget to use Frumil

Do not take a double dose to make up for the dose you missed.

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 your 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 use too much Frumil

If you think that you have used too much Frumil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre by calling 0800 764 766, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using Frumil?

Things you should 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. 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.

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.

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.

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Frumil.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • 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) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Frumil contains

Active ingredients (main ingredient)	Furosemide 40mg Amiloride 5mg
Other ingredients (inactive ingredients)	Colloidal silicon dioxide Lactose monohydrate Magnesium stearate Maize starch Microcrystalline cellulose Purified talc Sodium starch glycollate Sunset yellow FCF
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Frumil looks like

Frumil tablets are orange, scored with FRUMIL on reverse side. Frumil tablets are supplied in blister packs of 28 tablets.

Who distributes Frumil

Distributed by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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