

FRUSEMIX-M

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 FRUSEMIX-M?

FRUSEMIX-M contains the active ingredient, which belongs to a group of medicines called diuretics. Diuretics are used to help the kidneys remove excess fluid from the body.

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

2. What should I know before I use FRUSEMIX-M?

Do not use if you have ever had an allergic reaction to FRUSEMIX-M 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 this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FRUSEMIX-M 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 FRUSEMIX-M?

The dose of FRUSEMIX-M may be different for each person and their medical condition. Your doctor will decide the right dose for you. FRUSEMIX-M is available as a 20mg tablet.

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

5. What should I know while using FRUSEMIX-M?

| | |
|--|--|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using this medicine.Make sure you drink enough water during any exercise and during hot weather when you are taking This medicine, especially if you sweat a lot. |
| Things you should be careful of | <ul style="list-style-type: none">If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.If you are using This medicine for a long period of time, you should check with your doctor to determine whether you should eat more potassium-containing foods or take potassium supplements. |
| Driving or using machines | <ul style="list-style-type: none">If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. If this happens, do not drive or operate machines |
| Drinking alcohol | <ul style="list-style-type: none">It is not recommended that you drink alcohol while taking This medicine. |
| Looking after your medicine | <ul style="list-style-type: none">Keep This medicine in a cool dry place, protected from light, where the temperature stays below 25°C in its original packaging. |

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

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking This medicine.

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.

You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

FRUSEMIX-M

Active ingredient(s): *Furosemide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FRUSEMIX-M. **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 FRUSEMIX-M.**

Where to find information in this leaflet:

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

1. Why am I using FRUSEMIX-M?

FRUSEMIX-M contains the active ingredient called which belongs to a group of medicines called diuretics. Diuretics are used to help the kidneys remove excess fluid from the body.

FRUSEMIX-M is used to treat several medical conditions, including:

- oedema (swelling of the body, ankles, feet, legs or even the brain or lungs due to excess fluid). This problem can also occur in cases of heart, liver or kidney disease.
- hypertension (high blood pressure).

This can occur by itself or in severe heart, liver or kidney disease.

Everyone has blood pressure. This pressure helps move your blood around your body. Your blood pressure may vary at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

FRUSEMIX-M may be taken alone or in combination with other medicines to treat your condition.

Ask your doctor if you have any questions about why FRUSEMIX-M has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

This medicine is not addictive.

2. What should I know before I use FRUSEMIX-M?

Warnings

Do not use FRUSEMIX-M if you are allergic to:

- this medicine or any of the ingredients listed at the end of this leaflet.
- medicines called sulphonamides (e.g. Some types of antibiotics which are also referred to as 'sulfur antibiotics') or sulfonyleureas which are medicines which can be used to treat diabetes

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not use FRUSEMIX-M if:

- have severe kidney and liver disease or have no urine output.
- low blood pressure, low sodium levels in your blood, low potassium levels in your blood, dehydration, hepatic coma or precoma
- are pregnant.
- are breastfeeding or plan to breast feed.
- for use for children unless your doctor has prescribed it. If the medicine is for a newborn child, tell your doctor if the baby was jaundiced.
- after the expiry date (EXP.) printed on the pack.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you have any of the following medical conditions:

- Liver problems
- Kidney problems
- Heart problems
- High cholesterol levels
- Asthma
- Diabetes
- Gout, a disease with painful, swollen joints
- Passing less urine than is normal for you.
- Difficulty passing urine.
- No production or no passing of urine
- Prostate problems
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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

- If you have not told your doctor about any of the above, tell them before you start taking FRUSEMIX-M.

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 should not be taken with FRUSEMIX-M. This includes large amounts of laxatives.

Some medicines may interfere with FRUSEMIX-M. These include:

- certain other fluid tablets or diuretic medicines
- 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, swelling and other symptoms of inflammation, including arthritis
- methotrexate, a medicine used to treat arthritis and some types of cancer.
- probenecid, a medicine used to treat gout.
- 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)
- cisplatin, a medicine used to treat cancer.
- theophylline, a medicine used to treat asthma.
- certain antibiotics, especially cephalosporins and aminoglycosides
- amphotericin, a medicine used to treat fungal infections.
- barbiturates, medicine used to treat epilepsy, to produce calmness, or to help you sleep.
- narcotic/strong pain killers such as codeine and morphine
- insulin and tablets used to treat diabetes.
- sucralfate, a medicine used to treat stomach ulcers.

- anticonvulsant medicines such as chloral hydrate or phenytoin
- corticosteroids such as cortisone, prednisone or dexamethasone
- medicines used to treat thyroid conditions.
- risperidone, an antipsychotic medication used to schizophrenia.
- medicines used during scans to see the images of your body.

These medicines may be affected by FRUSEMIX-M 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 FRUSEMIX-M.

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

4. How do I use FRUSEMIX-M?

How much to take.

The dose of FRUSEMIX-M may be different for each person and their medical condition. Your doctor will decide the right dose for you.

The recommended doses for:

Oedema

Adults: 20 to 80 mg as a single dose.

Children: 2 mg per kg per day up to a maximum of 6 mg per kg per day or 40 mg per day.

Hypertension

Adults: 20 to 40 mg twice daily.

How to take this medicine

Swallow the medicine with water.

If the dose is one-half tablet, there is a break line on the tablet to help you divide it.

When to take this medicine

This medicine should be taken either early in the day or in the morning and no later than 4 hours before retiring if a twice daily dose is required.

How long to take it

Continue taking This medicine as long as your doctor recommends it.

If you forget to use this medicine

If your dosing schedule is one dose a day, take the missed dose as soon as possible, but not later than 4 hours before bedtime. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

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

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

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

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

If you use too much FRUSEMIX-M (overdose)

If you think that you have used too much FRUSEMIX-M, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to Accident and Emergency at your nearest hospital.
- if you think that you or anyone else may have taken too much FRUSEMIX-M.

You should do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol (including any barbiturates or narcotics) which has been taken.

You may need urgent medical attention.

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

5. What should I know while using FRUSEMIX-M?

Things you should do

Tell your doctor if, for any reason you have not taken your medicine exactly as directed or if you feel it is not helping your condition.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily. Tell all doctors, dentists and pharmacists who are treating you that you are taking FRUSEMIX-M.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FRUSEMIX-M. If you plan to have a surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Immediately tell your doctor if you become pregnant while you are taking this medicine.

Tell your doctor if you have excessive vomiting or diarrhoea while taking FRUSEMIX-M or if you experience any of the following symptoms:

- Dry mouth or thirst
- Fainting
- Weakness, tiredness or drowsiness
- Muscle pain or cramps
- Fast heartbeat

- passing less urine than normal

If you experience these symptoms, you may be dehydrated because you are losing too much water.

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

If you do not drink enough water while taking FRUSEMIX-M, 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 FRUSEMIX-M.

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

If you are taking FRUSEMIX-M to treat high blood pressure, make sure you have your blood pressure checked when your doctor says to make sure FRUSEMIX-M is working properly.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking FRUSEMIX-M.

Things you should not do.

- Do not take any other medicines while you are taking FRUSEMIX-M without first telling your doctor.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not take FRUSEMIX-M for a longer time than your doctor has prescribed.
- Avoid prolonged exposure to direct sunlight.
- Do not change your dose without first checking with your doctor.
- Do not stop taking FRUSEMIX-M or lower the dose, without first checking with your doctor.

Stopping the medicine suddenly on your own accord may cause some unwanted effects or your condition may reappear.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FRUSEMIX-M affects you.

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 FRUSEMIX-M. 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 FRUSEMIX-M 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

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

The effects of alcohol could be made worse while taking FRUSEMIX-M. It is not recommended that you drink alcohol while taking FRUSEMIX-M.

If you are taking FRUSEMIX-M for a long period of time, you should check with your doctor to determine whether or not you should eat more potassium-containing foods or take potassium supplements. However, increasing the amount of potassium in your diet may not be necessary and could be harmful. Check with your doctor.

FRUSEMIX-M may cause your skin to become more sensitive to the sun. If this happens you should take care to wear protective clothing including a hat and sun block when you are outside. may [insert effect relevant to use of the medicine].

Things that may help your condition.

Some self-help measures suggested below may help your condition.

Alcohol – your doctor may advise you to limit your alcohol intake.

Diet – eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.

Exercise – regular exercise helps reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is a good exercise but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of program for you.

Salt- if you have high blood pressure, your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table.

Smoking – your doctor may advise you to stop smoking or at least to cut it down.

Weight – your doctor may suggest that you lose some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Talk to your doctor or pharmacist about these measures and for more information.

Looking after your medicine

Keep FRUSEMIX-M in a cool dry place, protected from light, where the temperature stays below 25°C in original container; for example, do not store it:

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

Keep it where young children cannot reach it.

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

Heat and dampness can destroy some medicines.

When to discard your medicine

If your doctor tells you to stop taking the tablets or they have passed their expiry date, ask your pharmacist what to do with any left over.

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?

Tell your doctor as soon as possible if you do not feel well while you are taking FRUSEMIX-M.

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">• Muscle pains or cramps• lethargy• vomiting or nausea• drowsiness or a lack of energy• fever• loss of appetite• dry mouth• diarrhoea• blurred vision or impaired vision.• skin rashes.• Confusion• ringing or buzzing in the ears• Unusual bleeding or bruising under the skin.• restlessness | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">• usual bruising• Irregular or fast heartbeat• Passing less urine than is normal for you.• Severe stomach pain, often with nausea or vomiting• Severe dizziness or a spinning sensation• Increased sensitivity to sunlight• 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. | <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> <p>Serious side effects are uncommon.</p> |

Very Serious side effects

| Very Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">• 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• fainting or having a rapid, weak pulse• 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 | <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, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

Do not be alarmed by this list of side effects.

You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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

What FRUSEMIX-M contains

FRUSEMIX-M 20mg Tablet

| | |
|---|---|
| Active ingredient (main ingredient) | Each tablet contains 20 mg of the active ingredient, furosemide |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• Lactose monohydrate• Maize starch• Pregelatinised maize starch• Sodium starch glycollate (type A)• Magnesium stearate |
| Potential allergens | This medicine contains sugars as lactose. It does not contain gluten, tartrazine or any other azo dyes. |

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

What FRUSEMIX-M looks like

FRUSEMIX-M 20 mg is a White to off-white round tablets, debossed with 'F2' on one side and plain on the other side. Available in bottles of 50, 100, 1000 tablets*.

* Not all strengths and/or pack sizes may be available.

Who distributes FRUSEMIX-M

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia
www.arrotex.com.au

The Australian Registration Numbers for FRUSEMIX-M are:

- FRUSEMIX-M 20 mg tablet bottle:
AUST R 186526

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