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 Furosemide – AFT?

Furosemide – AFT contains the active ingredient furosemide (frusemide). Furosemide – AFT is a diuretic which helps 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 Furosemide – AFT? in the full CMI.

2. What should I know before I use Furosemide – AFT?

Do not use if you have ever had an allergic reaction to Furosemide – AFT 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 Furosemide - AFT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Furosemide - AFT 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 Furosemide – AFT?

Furosemide - AFT solution for injections are normally administered to you by doctors or nurses in hospital

More instructions can be found in Section 4. How do I use Furosemide - AFT? in the full CMI.

5. What should I know while using Furosemide – AFT?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Furosemide – AFT. Make sure you drink enough water during any exercise and during hot weather when you are using Furosemide – AFT, especially if you sweat a lot 	
Things you should be careful of	 If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. If you are using Furosemide – AFT 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. 	
Driving or using machines	Furosemide – AFT may cause dizziness or light-headedness in some people. If this happens, do not drive or operate machines	
Drinking alcohol	It is not recommended that you drink alcohol while using Furosemide – AFT	
Looking after your medicine	 Furosemide – AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 30 °C protected from light. Furosemide – AFT should not be frozen. 	

For more information, see Section 5. What should I know while using Furosemide – AFT? in the full CMI.

6. Are there any side effects?

Some of the common and less serious side effects are dry mouth, blurred vision, spasms, headache, numbness in hands/ feet, light – headedness, diarrhea and unusual bleeding or bruising under the skin. Some of the uncommon/ rare and serious side effects are chest pain, sudden signs of allergy, fainting, lockjaw, yellowing of skin/ eyes, irregular or fast heartbeat, deafness, passing less urine than normal, increased sensitivity to sunlight and loss of control of your bladder or bowels.

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.

Furosemide – AFT^{e005836} Furosemide-AFT

Active ingredient: *furosemide (frusemide)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Furosemide – AFT. 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 Furosemide – AFT.

Where to find information in this leaflet:

- 1. Why am I using Furosemide-AFT?
- 2. What should I know before I use Furosemide-AFT?
- 3. What if I am taking other medicines?
- 4. How do I use Furosemide-AFT?
- 5. What should I know while using Furosemide-AFT?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Furosemide – AFT?

Furosemide – AFT contains the active ingredient furosemide (frusemide). Furosemide – AFT is a diuretic. A diuretic helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

Furosemide – AFT is used to treat swelling of the ankles, feet, legs or even the brain or lungs. This swelling is called edema and can occur in some heart, lung, liver or kidney conditions.

Furosemide – AFT may be used in some patients with more serious kidney problems who may have some fluid retention.

Furosemide – AFT may be given alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed Furosemide – AFT 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 Furosemide – AFT?

Warnings

Do not use Furosemide – AFT if you have:

- certain liver and kidney problems
- no production or no passing of urine
- low blood pressure (hypotension)
- low sodium levels in your blood
- low potassium levels in your blood
- dehydration

- jaundice or history of jaundice in newborns or infants
- hepatic coma or precoma

Do not use Furosemide – AFT if you are allergic to:

- this medicine or any of the ingredients listed at the end of this leaflet
- medicines called sulfonamides (e.g. 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 use Furosemide – AFT if you are pregnant.

Do not use Furosemide – AFT 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.

Do not use Furosemide – AFT after the expiry date (EXP) printed on the pack.

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

Do not use the medicine if the packaging is torn or shows signs of tampering.

Check with your doctor if you have allergies to:

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

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 <u>6</u>. <u>Are there any side effects?</u>

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

- 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

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

Pregnancy and breastfeeding

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

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

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

Furosemide – AFT 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.

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 Furosemide – AFT. This includes large amounts of laxatives.

Some medicines may interfere with Furosemide – AFT. These medicines may be affected by Furosemide – AFT, 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. These medicines 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 B (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

You should not eat large amounts of liquorice when you are using Furosemide – AFT.

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

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

4. How do I use Furosemide – AFT?

How to use it

Furosemide – AFT solution for injections are normally administered to you by doctors or nurses in hospital

When to use Furosemide – AFT

Furosemide – AFT solution for injections are normally given by doctors or nurses in hospital. If you are not sure when to receive it, ask your doctor or pharmacist.

If you use too much Furosemide - AFT

As Furosemide – AFT is given to you under the supervision of your doctor, it is unlikely that you will have too much.

However, if you experience any side effects after being given Furosemide - AFT, you should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital, or
- phone the Poisons Information Centre (by calling 13 11 26)

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

If you are given too much Furosemide – AFT, you may feel confused, dehydrated, dizzy or you may pass excessive urine.

5. What should I know while using Furosemide – AFT?

Things you should do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Furosemide – AFT.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Furosemide – AFT.

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

Your blood pressure may drop suddenly.

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

Tell your doctor if you have excessive vomiting or diarrhea while taking Furosemide – AFT or if you experience any of the following symptoms:

- dry mouth or thirst
- fainting
- weakness, tiredness or drowsiness
- muscle pain or cramps
- fast heart beat
- 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 using Furosemide – AFT, especially if you sweat a lot.

If you do not drink enough water while using Furosemide – AFT, 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 Furosemide – AFT. There may be some interference with the results of these tests.

Things you should 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 Furosemide – AFT. 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.

If you are using Furosemide – AFT 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.

Furosemide – AFT 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.

Things that may help your condition

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

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Furosemide – AFT affects you.

Diuretic medicines (including Furosemide – AFT) 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 lightheaded.

If this occurs, do not drive or operate machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol could be made worse while taking Furosemide – AFT. If you drink alcohol or take strong painkillers, dizziness or lightheadedness may be worse. It is not recommended that you drink alcohol while using Furosemide – AFT.

Looking after your medicine

Furosemide – AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 30 °C protected from light.

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
Bleeding – related: • Unusual bleeding or bruising under the skin Eye, ear, mouth – related: • Blurred or impaired vision	Speak to your doctor if you have any of these less serious side effects and they worry you.
 Ringing or buzzing in the ears Very dry mouth or unusual thirst Pain – related: Calf muscle spasms Muscle pains or cramps 	These are more common side effects of Furosemide –
Headache Body as a whole:	they are mild or short-lived.
 Weight loss Weakness or tiredness Numbness or tingling in the hands and/ or feet Fever Restlessness Confusion Drowsiness or a lack of energy Dizziness or light – headedness Vomiting or nausea Diarrhea 	

Serious side effects

Serious side effects	What to do	
Bleeding – related: • Bleeding or bruising more easily than normal, nose bleeds	as soon as possible if you notice any of these side effects. Fast heart beat These may be serious side effects of ringing in the ears Tas soon as possible if you notice any of these side effects. These may be serious side effects of Furosemide —	
Heart – related: • Irregular or fast heart beat		
Ear – related: • Deafness or ringing in the ears		
Skin – related: • Flaking or peeling of skin • Increased sensitivity to sunlight	tivity to sunlight attention. Serious side	
Pain – related: • Severe stomach pain, often with nausea and vomiting • Gout, a disease with painful, swollen joints	effects are uncommon.	

Body as a whole:

- Passing less urine than is normal for you
- Severe dizziness or a spinning sensation
- Symptoms of anemia 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
- Loss of control of your bladder or bowels (incontinence)

Very serious side effects

Serious side effects	What to do
 Allergy – related: 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 Red, often itchy spots similar to the rash seen in 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-centered marks. Those affected may have fever, sore throat, headache with or without diarrhea. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. These are very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare.
Pain – related:	
Chest pain	
Body as a whole:	
 Fainting or having a rapid, weak pulse Lockjaw Yellowing of the skin and/ or eyes (jaundice) 	

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 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

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

What Furosemide - AFT contains

Active ingredient	Furosemide (frusemide)
(main ingredient)	
Other ingredients	Sodium chloride, sodium
(inactive ingredients)	hydroxide, water for injection
Potential allergens	Nil

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

What Furosemide - AFT looks like

Furosemide – AFT is a colourless or light yellow, clear, sterile aqueous solution contained in a 2 mL amber glass ampoule.

(Aust R 355583).

Who distributes Furosemide - AFT

AFT Pharmaceuticals Pty Ltd. 113 Wicks Road, North Ryde, NSW 2113, Australia

Email: customer.service@aftpharm.com

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