Lasix[®] and Lasix[®] High Dose

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 taking Lasix?

Lasix contains the active ingredient furosemide. Lasix is a diuretic. It is used to help reduce the amount of excess fluid in the body. For more information, see Section <u>1</u>. <u>Why am I using Lasix?</u> in the full CMI.

2. What should I know before I take Lasix?

Do not take Lasix if you have ever had an allergic reaction to furosemide, sulfonamides (e.g. 'sulfur antibiotics'), sulfonylureas 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, are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take Lasix? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lasix and affect how it works. A list of these medicines is in Section <u>3. What if</u> <u>I am taking other medicines?</u> in the full CMI.

4. How do I take Lasix?

You can take Lasix oral solution with water. Lasix injections are normally administered to you by doctors or nurses in hospital. More instructions can be found in Section <u>4. How do I take Lasix?</u> in the full CMI.

5. What should I know while taking Lasix?

Things you should do	 Remind any doctors, dentists or pharmacists that you are taking Lasix. Make sure you drink enough water during any exercise and during hot weather when you are taking Lasix, especially if you sweat a lot. Tell your doctor straight away if you become pregnant or intend to become pregnant.
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Things you should not do	 Do not eat large amounts of liquorice or take large amounts of laxatives while you are taking Lasix.
Things to be careful of	 If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. If you take Lasix for a long time, check with your doctor to determine whether or not you should eat more potassium-containing foods or take potassium supplements. If your skin becomes more sensitive to the sun, wear protective clothing, including a hat and sun block when you are outside.
Driving or using machines	 Lasix 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 taking Lasix.
Looking after your medicine	 Lasix oral solution should be stored in the original bottle in a cool dry place where the temperature stays below 25°C until ready to use. Lasix injection is usually stored in the pharmacy or on the ward in a cool dry place, protected from light, where the temperature stays below 25°C.

For more information, see Section <u>5. What should I know</u> while taking Lasix? 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), lockjaw, fainting or a rapid, weak pulse. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Lasix[®] and Lasix[®] High Dose

Active ingredient(s): furosemide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lasix. 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 Lasix.

Where to find information in this leaflet:

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

1. Why am I taking Lasix?

Lasix contains the active ingredient furosemide.

Lasix is a diuretic. A diuretic helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

Lasix is used to treat swelling of the ankles, feet, legs or even the brain or lungs.

This swelling is called oedema and can occur in some heart, lung, liver or kidney conditions.

Lasix may be used in some people with more serious kidney problems who may have some fluid retention.

Lasix may also be used to lower high blood pressure (which is also called hypertension).

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.

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

Your doctor may have prescribed Lasix for another purpose.

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

2. What should I know before I take Lasix?

Warnings

Do not take Lasix if you:

• are allergic to furosemide, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

 are allergic to 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.

Your doctor will know which medicines are sulfonamides or sulfonylureas.

- have allergies to any other substances, such as foods, preservatives or dyes
- have certain kidney problems
- have no production or no passing of urine
- have low blood pressure (hypotension)
- have low sodium levels in your blood
- have low potassium levels in your blood
- have dehydration
- have certain liver problems
- have hepatic coma or precoma

 have jaundice or history of jaundice in newborns or infants.

Check with your doctor if you have:

- liver problems
- kidney problems
- heart problems
- high cholesterol levels
- asthma
- diabetes
- gout, a disease with painful, swollen joints
- been passing less urine than is normal for you
- difficulty passing urine
- no production of urine
- prostate problems
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys
- any other medical conditions or take any medicines for any other condition.

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 take Lasix.

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. Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take Lasix if you are pregnant.

Check with your doctor if you are pregnant or intend to become pregnant. Lasix is not recommended to be used during pregnancy. If there is a need to consider Lasix during your pregnancy, your doctor will discuss the risks and benefits of taking it if you are pregnant.

Do not take Lasix if you are breastfeeding or planning to breastfeed.

The active drug, furosemide, passes into breast milk and there is a possibility your baby may be affected.

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

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 Lasix and affect how it works.

These include:

- certain antibiotics, especially some cephalosporins and aminoglycosides
- amphotericin B, a medicine used to treat fungal infections

- sucralfate, a medicine used to treat stomach ulcers
- barbiturates, medicine used to treat epilepsy, to produce calmness, or to help you sleep
- anticonvulsant medicines such as chloral hydrate or phenytoin
- lithium, a medicine used to treat mood swings and some types of depression
- risperidone, an antipsychotic medication
- corticosteroids such as cortisone, prednisone or dexamethasone
- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and aspirin, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- narcotic/strong pain killers such as codeine and morphine
- methotrexate, a medicine used to treat arthritis and some types of cancer
- probenecid, a medicine used to treat gout
- cisplatin, a medicine used to treat cancer
- insulin and tablets used to treat diabetes
- 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
- medicines used in emergency situations such as adrenaline (epinephrine) and noradrenaline (norepinephrine)

- medicines used to relax muscles before or during surgery
- medicines used during scans to see the images of your body
- theophylline, a medicine used to treat asthma
- levothyroxine, a medicine used to treat thyroid conditions.

Do not take large amounts of laxatives while you are taking Lasix.

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

4. How do I take Lasix?

How much to take

Oral solution:

- Adults: the usual initial adult daily dose is 20 to 80 mg.
- Infants and children: the usual initial dose of oral Lasix for infants and children is 2 mg/kg body weight given as a single dose.
- Your doctor will select a dose when they prescribe Lasix for you or your child. This depends on your/your child's condition.
- Depending on your/your child's response, your doctor may adjust the dose.
- 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 provided and take Lasix until your doctor tells you to stop.

Lasix injections:

• The treating doctor will decide on the dose that is most suitable.

When to take Lasix

Oral solution:

- Lasix oral solution is usually taken once or twice a day.
- Take Lasix oral solution on an empty stomach. For example, one hour before food or two hours after food.
 Food can interfere with its absorption.
- You can take Lasix oral solution with water.
- Take Lasix oral solution 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 Lasix oral solution to be taken once a day, it is best done in the morning, for example, before breakfast.
- If you are taking Lasix oral solution more than once a day, take your first dose immediately before breakfast

and take your last dose around 2:00 pm (on an empty stomach), unless your doctor tells you otherwise.

• Lasix 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 2:00 pm, there may be less chance that your sleep is disturbed.

Injections:

• Lasix injections are normally given by doctors or nurses in hospital. They will also tell you how long it will take to give the medicine. Several doses may be needed.

How long will Lasix need to be taken/given?

Oedema

Continue taking or receiving Lasix for as long as your doctor tells you.

The medicine helps control your condition and lowers the fluid build-up in your body.

Hypertension

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

The medicine helps control your blood pressure, but it does not cure it. Continue taking the medicine until your doctor tells you to stop.

Ask your doctor if you are not sure how long to take Lasix.

If you forget to take Lasix

Lasix should be taken regularly at the same time each day.

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 doctor or pharmacist for hints.

If you take too much Lasix

If you think that you have taken too much Lasix, you may need urgent medical attention. If you take too much Lasix, you may feel confused, dehydrated, dizzy or you may pass excessive urine.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), 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.

5. What should I know while taking Lasix?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Lasix.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Lasix.
- If you plan to have a surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine. Your blood pressure may drop suddenly.
- Make sure you drink enough water during any exercise and during hot weather when you are taking Lasix, especially if you sweat a lot.

If you do not drink enough water while taking Lasix, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly and you may become dehydrated. 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 Lasix. There may be some interference with the results of these tests.
- If you are taking Lasix to treat high blood pressure, make sure you have your blood pressure checked when your doctor says to make sure Lasix is working properly.

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 Lasix. 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 taking Lasix 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.
- Lasix 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.

Call your doctor straight away if you:

- become pregnant while you are taking this medicine
- if you have excessive vomiting or diarrhoea while taking Lasix 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.

Things you should not do

- Do not eat large amounts of liquorice while you are taking Lasix.
- Do not stop taking this medicine suddenly.
- Do not change the dosage without checking with your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.

Things that may help your condition

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Limiting 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.
- Watching salt intake 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.
- Reducing 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 Lasix affects you.

Lasix 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.

Do not drive, operate machinery, or do anything else that could be dangerous if this occurs.

Drinking alcohol

Tell your doctor if you drink 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 Lasix. It is not recommended that you drink alcohol while taking Lasix.

Lasix oral solution contains ethanol (alcohol) 0.5 g per 5 mL dose, which is equivalent to 12.7 mL of beer or 5.3 mL of wine per 5 mL dose.

Looking after your medicine

Keep your Lasix oral solution in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 25°C; for example, do not store it:

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

Keep your Lasix oral solution in the bottle until it is time to take it. If you store your Lasix oral solution out of the container it may not keep well.

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.

Lasix injection is usually stored in the pharmacy or on the ward. The injection is kept in a cool dry place, away from moisture, heat or sunlight, where the temperature stays below 25°C. The expiry date will be checked that it has not passed.

When to discard your medicine

Oral solution

Use within 8 weeks of opening the bottle.

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 take this medicine after the expiry date printed on the bottle. Do not take this medicine if the packaging is torn or shows signs of tampering.

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	What to do
 Alertness and sleep- related: headache dizziness or light- headedness drowsiness or a lack of energy restlessness confusion. Infection-related: 	Speak to your doctor if you have any of these less serious side effects and they worry you. These are more common side effects of Lasix. Mostly they are mild or short-lived.
 fever. Sight, hearing, smell, taste or touch-related: 	
 ringing or buzzing in the ears 	

Less serious side effects

Less serious side effects	What to do
 blurred or impaired vision 	
 very dry mouth or unusual thirst. 	
Stomach and gut- related:	
 vomiting or feeling sick (nausea) 	
• diarrhoea.	
Skin and muscle-related:	
 unusual bleeding or bruising under the skin 	
 calf muscle spasms 	
 weakness or tiredness 	
 muscle pains or cramps 	
 numbness or tingling in the hands and/or feet. 	
Other:	
• weight loss.	

Serious side effects

Serious side effects	What to do
Alertness and sleep- related:	Call your doctor as soon as possible if you notice any of the following.

Serious side effects	What to do
 severe dizziness or a spinning sensation. Bleeding-related: nose bleeds bleeding or bruising more easily than normal. Hearing-related: 	These may be serious side effects of Lasix. You may need urgent medical attention. Serious side effects are uncommon.
 deafness, ringing or buzzing in the ears. 	
Heart-related:	
 irregular or fast heartbeat. 	
Infection-related:	
 frequent infections such as fever, severe chills, sore throat or mouth ulcers. 	
Skin and muscle-related:	
 increased sensitivity to sunlight flaking or peeling of the skin gout, a disease with painful, swollen joints. Stomach and gut- 	
related:	

Serious side effects	What to do
 severe stomach pain, often with nausea or vomiting. 	
Other:	
 symptoms of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale 	
 loss of control of your bladder or bowels (incontinence) 	
 passing less urine than is normal for you. 	

Very serious side effects

Very 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, 	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

Very serious side effects	What to do
wheezing or trouble breathing. Skin-related:	attention or hospitalisation. These side effects are very rare.
 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). 	
Pain-related:	
 chest pain. 	
Other:	
 lockjaw fainting or having a rapid, weak pulse. 	

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 <u>www.tga.gov.au/reporting-problems</u> in Australia, or in New Zealand <u>https://pophealth.my.site.com/</u> <u>carmreportnz/s/</u>. 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 Lasix contains

Active ingredient	Lasix oral solution:
(main ingredient)	Lasix oral solution contains furosemide 10 mg/mL.
	Lasix injections:

	Lasix 20 mg/2mL, Lasix 40mg/4mL and Lasix High Dose 250mg/25 mL injection ampoules contain furosemide 10 mg/mL.
Other ingredients	Lasix oral solution:
(inactive ingredients)	 ethanol (alcohol) 0.5 g per 5 mL dose, which is equivalent to 12.7 mL of beer or 5.3 mL of wine per 5 mL dose. sorbitol solution (70 per cent) (non-crystallising) glycerol sodium hydroxide methyl hydroxybenzoate propyl hydroxybenzoate quinoline yellow sunset yellow FCF Trusil orange flavour 10814413 (P.I. No. 106046) purified water. Lasix injections: sodium chloride sodium hydroxide water for injections.

	Contains 0.16 mmol/mL of sodium.
	Lasix High Dose injections:
	 mannitol
	 sodium hydroxide
	 water for injections.
	Contains 0.03 mmol/mL of sodium.
Potential allergens	Lasix oral solution:
	 alcohol
	 hydroxybenzoates.

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

What Lasix looks like

Lasix oral solution: Lasix oral solution is a clear, yellow liquid with the odour and taste of orange. It is supplied in a glass, amber-coloured bottle of 30 mL (AUST R 232815).

Lasix injection: Lasix injection is a clear, colourless liquid presented in a glass, amber-coloured ampoule. It is supplied in packs of 5 ampoules of 20 mg in 2 mL* solution (AUST R 12404) or 40 mg in 4 mL* solution (AUST R 76767).

*Not available in New Zealand.

Lasix High Dose injection: Lasix High Dose Injection is a clear, colourless liquid presented in a glass, ambercoloured ampoule. It is supplied in packs of 6 ampoules of 25 mL solution (AUST R 12408).

Who distributes Lasix

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113 Freecall: 1800 818 806 Email: medinfo.australia@sanofi.com Distributed in New Zealand 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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