UREMIDE®

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 UREMIDE?

UREMIDE contains the active ingredient furosemide. It is used to help reduce the excess fluid in the body.

For more information, see Section <u>1. Why am I taking UREMIDE?</u> in the full CMI.

2. What should I know before I take UREMIDE?

Do not take UREMIDE 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, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take UREMIDE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with UREMIDE 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 take UREMIDE?

Swallow the tablets with a glass of water. More instructions can be found in Section <u>4. How do I take UREMIDE?</u> in the full CMI.

5. What should I know while taking UREMIDE?

Things you should do

- Remind any doctor, dentist or pharmacists that you are taking UREMIDE.
- Make sure you drink enough water during any exercise and during hot weather when you are taking UREMIDE, 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	 Do not eat large amounts of liquorice or take large amounts of laxatives while you are taking UREMIDE.
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 UREMIDE 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	 UREMIDE 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 UREMIDE.
Looking after your medicine	 Store your UREMIDE tablets in the original container, in a cool dry place where the temperature stays below 30°C.

For more information, see Section <u>5. What should I know while taking UREMIDE?</u> 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</u>. Are there any side effects? in the full CMI.

UREMIDE®

Active ingredient(s): furosemide

Consumer Medicine Information (CMI)

This leaflet provides important information about using UREMIDE. 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 UREMIDE.

Where to find information in this leaflet:

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

1. Why am I taking UREMIDE?

UREMIDE contains the active ingredient furosemide.

UREMIDE belongs to a family of medicines called diuretics. A diuretic helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

UREMIDE 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.

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

UREMIDE 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 be different 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.

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

Your doctor may have prescribed UREMIDE for another purpose.

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

This medicine is not addictive.

2. What should I know before I take UREMIDE?

Warnings

Do not take UREMIDE if:

you are allergic to:

- o furosemide
- 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.
- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes

Some of the symptoms of an allergic reaction include:

- skin rash, itching,
- shortness of breath
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing

If you are not sure whether you should start taking this medicine, talk to your doctor.

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.

Restricting your salt intake may lead to increased side effects.

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

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>. Are there any side effects?

Pregnancy and breastfeeding

Do not take UREMIDE if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

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

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

Do not take UREMIDE 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.

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

Your doctor will discuss the risks and benefits of taking UREMIDE if you are breastfeeding or planning 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 UREMIDE and affect how it works. These include:

 certain antibiotics, especially some cephalosporins and aminoglycosides

- amphotericin B (amphotericin), a medicine used to treat fungal infections
- sucralfate, a medicine used to treat stomach ulcers
- barbiturates, medicines 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 used to treat schizophrenia
- 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 UREMIDE.

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

4. How do I take UREMIDE?

How much to take

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

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

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and how you respond to this medicine.

The usual initial dose for:

Oedema

Adults: 20 to 80 mg as a signal dose once a day.

Infants and children: 3 mg/kg per day up to a maximum of 6 mg/kg per day.

Hypertension

Adults: 80 mg per day divided into 40 mg twice a day.

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, UREMIDE may not work as well and your problem may not improve.

When to take UREMIDE

UREMIDE is usually taken once or twice a day.

Take UREMIDE on an empty stomach. For example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of UREMIDE.

Take UREMIDE 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 UREMIDE to be taken once a day, it is best done in the morning, for example, before breakfast.

If you are taking UREMIDE 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.

UREMIDE 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.

How long to take it

Oedema

Continue taking UREMIDE 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 UREMIDE 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 or pharmacist if you are not sure how long to take the medicine for.

How to take UREMIDE

Swallow the tablets with a glass of water.

If you forget to take UREMIDE

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

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 your next dose when you are meant to.

If there is still a long time to go before your next dose, take the missed dose 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 UREMIDE

If you think that you or anyone else has taken too much UREMIDE, urgent medical attention maybe needed. If you take too much UREMIDE, 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) for advice, 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 UREMIDE?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking UREMIDE.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking UREMIDE.
- 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 UREMIDE, especially if you sweat a lot.

If you do not drink enough water while taking UREMIDE, 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 UREMIDE. There may be some interference with the results of these tests.
- If you are taking UREMIDE to treat high blood pressure, make sure you have your blood pressure checked when your doctor says to make sure UREMIDE 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 UREMIDE. 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 UREMIDE for a long period of time, you should check with your doctor to determine whether or not you should eat more potassiumcontaining 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.
- UREMIDE 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.

Tell your doctor immediately if you:

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

Things you should not do

- Do not eat large amounts of liquorice while you are taking UREMIDE.
- 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.

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how UREMIDE affects you.

UREMIDE 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 UREMIDE. It is not recommended that you drink alcohol while taking UREMIDE.

Looking after your medicine

Keep your tablets in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 30°C; for example, do not store it:

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

Heat and dampness can destroy some medicines.

Keep your tablets in the original container until it is time to take them.

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.

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

Less serious side effects	What to do
Alertness and sleep-related:	Speak to your doctor if you have any of these
 headache dizziness or lightheadedness drowsiness or a lack of energy restlessness confusion. Infection-related: fever. Sight, hearing, smell, taste or touch related: ringing or buzzing in the ears blurred or impaired vision very dry mouth or unusual thirst. Stomach and gutrelated: vomiting or feeling sick (nausea) 	less serious side effects and they worry you. These are more common side effects of UREMIDE. Mostly they are mild or short-lived.

Less serious side effects	What to do
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: • severe dizziness or a	Call your doctor as soon as possible if you notice any of the following.
 spinning sensation. Bleeding-related: nose bleeds bleeding or bruising more easily than normal. Hearing-related: 	These may be serious side effects of UREMIDE. You may need urgent medical attention. Serious side effects are uncommon.
 deafness, ringing or buzzing in the ears. 	

Serious side effects	What to do
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:	
 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 	

Serious side effects	What to do
 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
 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. Skin-related: 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 	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 hospitalisation. These side effects are very rare.

Very serious side effects	What to do
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:	
lockjawfainting 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 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 UREMIDE contains

Active ingredient (main ingredient)	furosemide (40 mg per tablet)
Other ingredients (inactive ingredients)	 lactose monohydrate maize starch pregelatinised maize starch magnesium stearate.
Potential allergens	sugars as lactosesulfites

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

What UREMIDE looks like

UREMIDE is an 8 mm flat bevelled edged white tablet marked FE/40 on one side, alpha symbol on the reverse (AUST R 17704).

Each pack contains 30 or 100 tablets.

Who distributes UREMIDE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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