

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine which is available in tablets of three different strengths. Urex-M is a 20-mg tablet, Urex is a 40 mg tablet, and Urex Forte is a 500 mg tablet.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking Urex against the benefits they expect it will have.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Urex is used for

The active ingredient in Urex is called frusemide which belongs to a group of medicines called diuretics. Diuretics are used to help the kidneys remove excess fluid from the body.

Urex is used to treat a number of 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.

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

Ask your doctor if you have any questions about why Urex 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.

Before you take it

When you must not take it

Do not take Urex if you are allergic to:

- **this medicine or any of the ingredients listed at the end of this leaflet**
- **medicines called sulphonamides (eg. 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 take Urex if you have severe kidney and liver disease or have no urine output.

Do not take Urex if you have low blood pressure, low sodium levels in your blood, low potassium levels in your blood, dehydration, hepatic coma or precoma

Do not take Urex if you are pregnant.

Do not take Urex if you are breastfeeding or plan to breast feed.

Do not give it to children unless your doctor has prescribed it. If the medicine is for a newborn child, tell your doctor if the baby was jaundiced.

Do not take Urex after the expiry date (EXP.) printed on the pack.

Do not take Urex if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any other foods, dyes or preservatives.

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

- 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 pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of you taking Urex during pregnancy.

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

Urex 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 breast-feeding 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 Urex.

Taking other medicines

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

Some medicines should not be taken with Urex. This includes large amounts of laxatives.

Some medicines may interfere with Urex. 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
- sucralate, 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 UREX, 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 Urex.

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

How to take it

How much to take

The dose of Urex 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. The dose may be increased in exceptional cases up to 400 mg per day.

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.

Only in unusual cases of reduced glomerular filtration (kidney disease) will a high dose using Urex Forte be required.

How to take it

Swallow the medicine with water.

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

When to take it

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 Urex as long as your doctor recommends it.

If you forget to take it

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 take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Urex. 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 Urex, you may feel confused, dehydrated, dizzy or you may pass excessive urine.

While you are taking it

Things you must 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 Urex.

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

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 Urex 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 taking Urex, especially if you sweat a lot.

If you do not drink enough water while taking Urex, 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 Urex. There may be some interference with the results of these tests.

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

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking Urex.

Things you must not do

Do not take any other medicines while you are taking Urex without first telling your doctor.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not take Urex 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 Urex 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.

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 Urex. 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 Urex 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.

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

If you are taking Urex 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.

Urex 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.

- **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.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- Very dry mouth or unusual thirst
- diarrhoea
- headache

- dizziness
- Weight loss
- Weakness or tiredness
- Numbness or tingling in the hands and/or feet
- Calf muscle spasms
- 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

These are more common side effects of Urex. Mostly they are mild or short-lived.

Tell your doctor immediately if you notice any of the following:

- usual bruising
- Irregular or fast heart beat
- 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

These may be serious side effects of Urex. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

these are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything else that is 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.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Urex in a cool dry place, protected from light, where the temperature stays below 30°C.

Keep it where children cannot reach it.

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

Do not store it or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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.

Product description

What it looks like

Urex-M 20 mg is a white to off-white plain round uncoated tablet. Available in bottles of 50 tablets.

Urex 40 mg is a white round biconvex tablet, one side plain and the other scored. Available in blister packs of 100 tablets.

Urex Forte 500 mg is a white round uncoated tablet with one side plain and the other scored with a break line. Available in blister packs of 50 tablets.

Ingredients

Urex-M

Each Urex-M tablet contains 20 mg of the active ingredient, furosemide (frusemide).

It also contains the inactive ingredients lactose monohydrate, maize starch and magnesium stearate.

Urex

Each Urex tablet contains 40 mg of the active ingredient, furosemide (frusemide).

It also contains the inactive ingredients lactose monohydrate, maize starch and magnesium stearate.

Urex Forte

Each Urex Forte tablet contains 500 mg of the active ingredient, furosemide (frusemide).

It also contains the inactive ingredients lactose monohydrate, maize starch, magnesium stearate, maltodextrin and colloidal anhydrous silica.

This medicine contains sugars as lactose. It does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

The Australian Registration Numbers for Urex are:

- Urex-M 20 mg tablet bottle:
AUST R 13475
- Urex 40 mg tablet blister pack:
AUST R 34494
- Urex Forte 500 mg tablet blister pack:
AUST R 196972

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