

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:

- frusemide or other sulphonamide type medications
- any of the ingredients listed at the end of this leaflet.

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:

- inflammation of the prostate (if you are a male)
- low blood pressure and/or take any medications to treat low blood pressure
- any medical condition requiring you to take lithium.
- you are on a salt restricted diet
- you are taking antibiotics
- you are taking other antihypertensive drugs
- you suffer from gout
- you have diabetes or high cholesterol levels.
- you are at risk of low blood pressure
- you have liver, kidney or heart disease
- you are taking phenytoin.
- you have asthma.
- Passing less urine than is normal for you
- Difficulty passing urine
- 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.

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 may interfere with Urex. These include:

- drugs which are used to treat allergic conditions (e.g. corticosteroids)
- drugs used to treat some types of mental illnesses (e.g. lithium carbonate)
- medicines used to treat constipation
- some medicines including aspirin or anti-arthritis medication such as indomethacin.
- some common antibiotics e.g. aminoglycosides, cephalosporin, cephalothin or cephaloridine
- some medications used to treat high blood pressure (e.g. ACE inhibitors such as Asig)
- alcohol, barbiturates or narcotics. These may cause fainting or dizziness when getting up from a sitting position.
- carbenoxolone, used to treat gastric ulcers
- phenytoin, used to treat epilepsy.
- medicines used to treat heart failure
- methotrexate, a medicine used to treat arthritis
- diuretic medicines
- medicines used to relax muscles before or during surgery
- cisplatin, a medicine used to treat cancer
- theophylline, a medicine used to treat asthma
- amphotericin, a medicine used to treat fungal infections
- narcotic
- sueralfate, a medicine used to treat stomach ulcers
- medicines used to treat thyroid conditions
- risperidone, an antipsychotic medication used to schizophrenia
- medicines used during scans to see the images of your body.

DO NOT TAKE UREX IF YOU ARE TAKING THIS MEDICATION.

- probenicid, used to treat gout
- methotrexate
- antidiabetics such as metformin, diabex or rastiron
- pressor amines such as adrenaline and noradrenaline
- ingestion of large amounts of liquorice.

These medicines may be affected by Urex or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or 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.

Symptoms of overdose may include weakness, dizziness, lethargy, nausea, vomiting, diarrhoea, anorexia, sweating, mental confusion, blurred vision, tingling in the arms or legs, restlessness, headache, tinnitus (ringing in the ears), cramping, constipation, and symptoms associated with electrolyte and fluid depletion and hypotension.

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

Be careful drinking alcohol while taking Urex.

If you drink alcohol, it could make some unwanted side effects of Urex worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking this medicine.

Do not drive or operate machinery until you know how Urex affects you.

Urex may cause dizziness in some people and therefore may affect alertness. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Some people may experience side effects such as nausea, headache, dizziness, faintness or lightheadedness when standing up after resting, which may further affect the risk when using dangerous machinery.

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.

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:

- nausea (feeling sick)
- diarrhoea
- constipation
- abdominal pain
- 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
- drowsiness or a lack of energy
- fever
- loss of appetite
- dry mouth
- diarrhoea
- blurred vision
- skin rashes.

These are common side effects.

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
- sore throat
- feeling dizzy when getting up quickly
- swelling in the arms or legs
- yellowing of the skin or eyes
- tinnitus (ringing in the ears)
- muscle spasms
- severe or persistent headache
- shortness of breath
- severe palpitations
- confusion or vision problems
- severe diarrhoea.

These are rare, serious side effects. Your doctor may lower the dose to help control serious side effects and decide on necessary tests to monitor any of the above problems.

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

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

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 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

This leaflet was revised in January 2018