

Package leaflet: Information for the user
Furosemide 4mg/ml Oral Solution
Furosemide 8mg/ml Oral Solution
Furosemide 10mg/ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Furosemide 4mg/ml, 8mg/ml or 10mg/ml Oral Solution but it will be referred to as Furosemide throughout this leaflet.

What is in this leaflet

1. What Furosemide is and what it is used for
2. What you need to know before you take Furosemide
3. How to take Furosemide
4. Possible side effects
5. How to store Furosemide
6. Contents of the pack and other information

1. What Furosemide is and what it is used for

Furosemide belongs to a group of medicines called diuretics or water tablets.

Furosemide can be used to remove the levels of excess water in the body caused by heart, lung, kidney, liver or blood vessel problems.

2. What you need to know before you take Furosemide

Do not take Furosemide if:

- you are allergic (hypersensitive) to Furosemide, sulphonamides or any other ingredients in this liquid (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have symptoms of weakness, difficulty in breathing and light-headedness. This could be a sign of having too little water in the body
- you are dehydrated
- you have been told by your doctor you have low blood volume. Sign of low blood volume can include your skin turning pale, feeling dizzy, faint or nauseous and feeling very thirsty.
- you are not passing water (urine) at all or only a small amount each day
- you have kidney failure or liver problems
- you have a severe change in blood salts, such as very low potassium level or low sodium levels. You may notice signs of this such as muscle cramps, weakness and tiredness.
- you are allergic to antibacterials called sulphonamides

- you are breast-feeding (see section Pregnancy and Breast-feeding).

Patients in a coma should not be given this medicine.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Furosemide.

Warnings and precautions

Talk to your doctor or pharmacist before taking Furosemide if:

- you have low blood pressure. The signs of this includes dizziness, feeling less alert than usual, fainting and general weakness
- you are elderly, if you are on other medications which can cause your blood pressure to drop and if you have other medical conditions that may cause your blood pressure to drop
- you have difficulty in passing water (urine), particularly if you have an enlarged prostate gland
- you have gout
- you have hepatorenal syndrome. This is when you develop kidney failure as a result of sever liver failure
- you have low levels of protein in the blood. The signs of this may include swelling, feeling sick (nausea) or being sick (vomiting), diarrhoea and stomach pain
- you have brain disorders affecting your nervous system, or a condition called porphyria. This is a disorder that can cause skin blisters, pain in and around the stomach area (abdomen)
- you have diabetes
- you are an elderly patient with dementia and are also taking risperidone.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Furosemide.

Having tests whilst on Furosemide

While you are taking this medicine, your doctor may give you regular blood tests. Your doctor will do this to monitor levels of salts, minerals and glucose in your blood and to check that your kidneys are working properly.

Other medicines and Furosemide

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including herbal medicines. This is because Furosemide, the main ingredient of this medicine, can affect the way some other medicines work. Also some medicines can affect the way Furosemide works.

Tell your doctor if you are taking any of these medicines:

- medicines used to treat high blood pressure known as angiotensin converting enzyme (ACE) inhibitors or Angiotensin-II receptor antagonists, such as captopril, losartan
- medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin
- medicines used to treat high blood pressure, angina and heart failure known as beta blockers such as, propranolol, atenolol, sotalol
- medicines used to treat high blood pressure and other medicines used to remove water from the body known as diuretics, such as acetazolamide and metolazone
- digoxin used to treat heart failure and unusual heart rhythms

- medicines used to treat unusual heart beats, such as amiodarone, disopyramide, flecainide, lidocaine and mexiletine
- a medicine used to prevent atrial fibrillation, unwanted clotting and stroke, called warfarin
- a medicine used to treat high cholesterol, called clofibrate
- medicines used to treat pain and inflammation known as nonsteroidal anti-inflammatory drugs (NSAIDs), such as indometacin or salicylates such as aspirin
- medicines used to treat inflammation known as corticosteroids, such as prednisolone and dexamethasone
- medicines used to treat infections caused by bacteria, such as lymecycline, vancomycin, gentamicin, ceftriaxone and colistin
- medicines used to treat infections caused by fungus, such as amphotericin
- medicines used to treat infections caused by a virus, such as nelfinavir, ritonavir and saquinavir
- medicine used to prevent rejection after transplants, such as tacrolimus, ciclosporin
- medicines used to treat depression, such as reboxetine, amitriptyline and phenelzine
- medicines used to treat mental problems called ‘psychoses’, such as risperidone, amisulpride, sertindole, pimozide and chlorpromazine
- a medicine used to treat extreme mood swings, called lithium
- a medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD), called atomoxetine
- medicines used to treat epilepsy, such as carbamazepine, phenobarbital and phenytoin
- medicines to treat asthma, such as salmeterol, salbutamol and theophylline. These medicines also treat chronic obstructive pulmonary disease
- medicines used to treat blocked noses, such as ephedrine and xylometazoline
- a medicine used to treat mouth ulcers and problems with the digestive area of the stomach (the upper gastrointestinal area), called carbenoxolone
- medicines used to treat cancer, called cisplatin and methotrexate
- medicine used to treat constipation, such as laxatives
- a medicine used to treat gout, called probenecid
- potassium salts used to treat low potassium in the blood
- anything that contains large amount of liquorice
- a medicine used to treat stomach ulcers, called sucralfate. Do not take sucralfate within two hours of taking Furosemide. This is because the sucralfate can stop the Furosemide from working properly
- medicines used as injections before X-ray examinations (radiocontrast agent).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Furosemide.

Children and adolescents

This medicine should not be used in children and adolescents.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if

- You are pregnant or planning to become pregnant.
- You should not take this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate machinery whilst taking this medicine as this medicine may make you feel less alert than normal.

Furosemide contains:

This medicine contains ethanol (alcohol). Each ml of oral solution contains 83.2mg ethanol (alcohol) i.e. daily dose of 40mg Furosemide would include 332.8mg-832mg ethanol, equivalent to 8.32ml-20.8ml of beer or 3.47ml-8.67ml of wine depending upon the prescribed strength. It is harmful to those who suffer from alcoholism. You should be aware the product has alcohol in it if:

- you are pregnant or breast-feeding
- you have liver disease
- you have epilepsy
- you have had a brain injury or brain disease
- you are going to give this medicine to a child.

This medicine also contains liquid maltitol (E965). If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine.

3. How to take Furosemide

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 4mg, 8mg or 10mg of Furosemide in each 1ml
- take this medicine by mouth
- it is best to take your dose in the morning
- plan your doses so that they do not affect your personal activities and sleep
- ask your doctor or pharmacist to help you plan the best time to take this medicine.

Adults

The usual dose for adults is:

- 40mg each day
- take the dose prescribed by your doctor.

Older people:

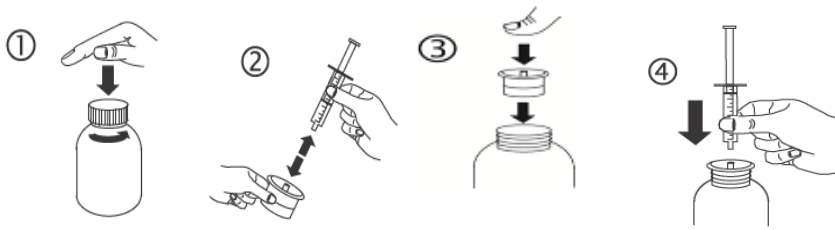
If you are an older person, your doctor may start you on a lower dose and gradually raise this dose.

Method of administration:

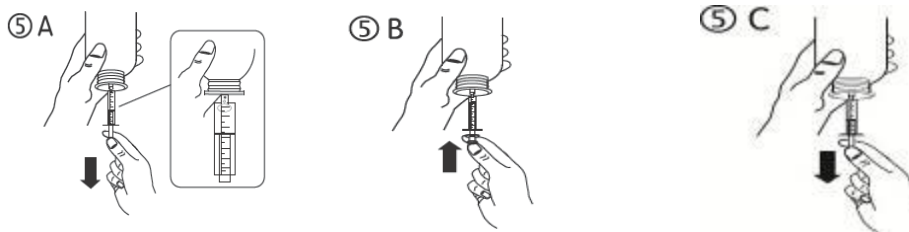
Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of syringe:

1. Open the bottle: press the cap and turn it anticlockwise (Figure 1).
2. Separate the adaptor from the syringe (Figure 2). Insert the adaptor into the bottle neck (Figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (Figure 4).



3. Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (Figure 5A) and then push the piston up in order to remove any possible air bubbles. (Figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 5C).



4. Turn the bottle the right way up (Figure 6A) Remove the syringe from the adaptor (Figure 6B).



5. Empty the contents of the syringe into the mouth of the patient by pushing the piston to the bottom of the syringe (Figure 7). Leave the syringe adaptor in place after first use. Close the bottle with the plastic screw cap. Wash the syringe with water and store in a clean place (Figure 8).



If you take more Furosemide than you should

If you take more of the medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Furosemide

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Furosemide can cause side effects, although not everybody gets them.

If you have an allergic reaction to Furosemide, see a doctor straight away.

An allergic reaction may include:

- any kind of skin rash
- difficulty in breathing, fever and collapse
- more long-term allergic reactions including swelling of the kidneys and blood vessels and particular sensitivity of the skin to sunlight and other sources of light such as sun-beds.

The other possible side effects are listed under headings of their frequency.

Very Common (may affect more than 1 in 10 people)

- Dehydration which reduces the normal water content of your body and upsets the balance of minerals. Symptoms include muscle spasm, weakness, twitching, or convulsions. Increased triglyceride levels may occur.

Common (affects 1 to 10 users in 100)

- Furosemide can cause an excessive depletion of body fluids by e.g. passing urine more often than normal and minerals (sodium, potassium,). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach
- If you have a shortage of sodium (sodium deficiency) you may experience cramp in the calf muscle, loss of appetite, listlessness, feeling of weakness, dizziness, drowsiness, confusion
- If you have a shortage of potassium (potassium deficiency): you may experience: muscular weakness and the inability to contract one or more muscles (paralysis), increased excretion of urine, heart problems, in the case of severe potassium deficiency: interference with the function of the intestine or confusion, which can result in coma
- During treatment with furosemide, the blood levels of cholesterol may rise and also blood levels of uric acid.

Uncommon (affects 1 to 10 users in 1,000)

- abnormal blood count accompanied by bruising and a tendency to bleed
- sensitivity to light (photosensitivity)
- involuntary leakage of urine
- in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood
- deafness (sometimes irreversible)
- eyesight may become disturbed
- gastrointestinal problems such as sensation of unease and discomfort in stomach with a urge to vomit or diarrhoea or constipation
- tiredness, weakness and muscle cramps
- increase creatinine and urea levels in the blood
- change in the ability to tolerate sugars.

Rare (affects 1 to 10 users in 10,000)

- abnormal blood count (white blood cell deficiency) accompanied by a increased susceptibility to infection
- increase in certain substances (eosinophilic cells) in the blood
- a crawling sensation on the skin, itching or tingling without any reason
- a life-threatening form of unconsciousness
- hearing disorders & ringing in the ears. These disorders are usually temporary in nature
- inflammation of a blood vessel
- acute kidney failure
- inflammation of the kidneys associated with blood in the urine, fever and pain in the sides
- shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances
- skin reactions with itching, red rashes or spots, blisters
- fever
- malaise
- minor mental disturbances.

Very rare (affects less than 1 user in 10,000)

- anaemia (a condition characterised by shortage of red blood cells)
- very severe blood abnormality (white blood cell deficiency) accompanied by a sudden high fever, severe throat pain and ulcers in the mouth
- certain liver function disorders
- increase in certain liver enzymes.

Not known

- acute generalised exanthematous pustulosis (an acute febrile drug eruption)
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- clots in the blood
- increase in certain liver enzymes or liver disease
- inflammation of the pancreas
- if you have a shortage of magnesium and calcium (magnesium and calcium deficiency) you may experience increased irritability of the muscles heart rhythm disturbances. lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright
- urinary incontinence can become worse if you have an urinary tract obstruction or urinary retention.

If furosemide is used in babies born too soon (prematurely), it can cause:

- Persistence of a blood channel that normally closes at or around birth. This may cause heart failure, failure to grow, shortness of breath and rapid pulse
- Kidney stones and/or calcium deposits in the body.

This medicine should not be used in babies.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; E-mail:

medsafety@hpra.ie in Ireland. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton box and label after 'Exp'.
- The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Discard 60 days after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Furosemide contains

The active ingredient is Furosemide.

Each ml of solution contains 4mg, 8mg or 10mg Furosemide.

The other ingredients are:

citric acid monohydrate (E330), ethanol, sodium hydroxide (E524), disodium phosphate, anhydrous (E339), liquid maltitol (E965), cherry flavour [containing propylene glycol (E1520)] and purified water.

This product is sugar free.

What Furosemide looks like and contents of the pack

Furosemide oral solution is a clear, colourless, greenish yellow to pale brown coloured solution with cherry flavour supplied in amber glass bottles with tamper evident child resistant plastic cap. The pack also contains 10ml oral syringe with 0.5ml graduation marks and a syringe adaptor.

Furosemide Oral Solution is supplied in bottles containing 100ml, 150ml and 300ml solution. Not all pack sizes may be marketed.

POM

Marketing Authorisation Holder:

Syri Pharma Limited t/a Thame Laboratories
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Dublin 2, D02 F206, Ireland.

Manufacturer:

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