

Package leaflet: Information for the patient
FUROSEMIDE 50 mg/5 ml Oral Solution
Furosemide 50 mg

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.

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 which reduce excess water (fluid retention) in the body by increasing urine production. Water can accumulate if you have a condition affecting your heart, lungs, kidney, liver or blood vessels. Furosemide 50 mg/5 ml Oral Solution is particularly useful for patients who cannot take tablets.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FUROSEMIDE

DO NOT take Furosemide:

- if you are allergic to furosemide or any of the other ingredients of this medicine (*listed in section 6*).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you are allergic to sulphonamides or sulphonamide derivatives, such as sulfadiazine or cotrimoxazole
- if you have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
- if you have too little potassium or sodium in your blood (shown in blood test)
- if you have severe liver problems (cirrhosis)
- if you have already taken furosemide in the past to treat failure to pass urine or kidney failure that is due to medicines or chemicals that are prone to cause kidney or liver damage or if you have kidney failure due to underlying liver disorders
- if you are not passing any water (urine) or you have been told by a doctor that you have kidney failure. In some types of kidney failure it is still okay to have this medicine. Your doctor will be able to decide
- if you have an illness called 'Addison's Disease'. This can make you feel tired and weak or if you are taking digitalis, used to treat heart problems
- if you have a disease called porphyria characterised by abdominal pain, vomiting or muscle weakness
- if you are breast-feeding.

Warning and precautions:

Talk to your doctor or pharmacist before taking Furosemide

- if you are elderly, or if you are on other medications which can cause a drop in blood pressure and if you have other medical conditions that can cause blood pressure to drop
- if you have low blood pressure or feel dizzy when you stand up
- if you feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- if you have low blood levels of essential minerals like sodium or potassium or you have acid base imbalance in the body identified by blood tests
- if you have difficulty in passing water, for example because of an enlarged prostate gland (males only)
- if you have diabetes
- if you have gout (characterised by painful joints due to elevated uric acid levels)
- if you have kidney or liver problems
- if you have low blood protein levels (hypoproteinaemia) as this may reduce the effect of the drug and increase the risk of ear damage
- if you have raised levels of calcium in the blood; careful monitoring of fluids and electrolyte levels are recommended
- if you have a risk of fall in blood pressure; or in case of premature infants as they may be more prone to developments of kidney stones
- if you are already on medicines like NSAIDs (used for inflammation and pain) or ACE inhibitors (medicines used to lower blood pressure)
- laboratory monitoring – it is recommended to undergo regular monitoring of blood levels for sodium, potassium, kidney function tests (blood urea nitrogen and creatinine levels), glucose, magnesium, calcium, chloride bicarbonate and uric acid
- regular monitoring is required to check for occurrence of blood dyscrasias (abnormal or imbalance in blood components), damage or any symptom that may occur particularly to you
- if you are an elderly patient with dementia and are also taking risperidone.

Do not use Furosemide:

- if you are planning to undergo a procedure that includes the use of radiocontrast (as taking Furosemide may increase the risk of kidney damage)

Other medicines and Furosemide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

- tell your doctor if you are taking the below medicines as the dose of these may need to be changed to avoid the risk of excessive lowering of blood pressure. Other blood pressure lowering agents (cardiac glycoside e.g. digoxin, other diuretics that help you pass more urine; or other blood pressure lowering agents)
- if you are taking any drugs that can be harmful to your kidneys
- if you have low levels of potassium or magnesium in your blood indicated by the blood counts

A large number of drugs can interact with furosemide which can significantly alter their effects. These drugs include:

- medicines such as Ramipril, enalapril, perindopril (called 'ACE Inhibitors') or losartan, candesartan, irbesartan (called angiotensin II receptor antagonists)
- anti-psychotics (medicines used to treat mental disorders) such as tricyclic antidepressants, hypnotics and anxiolytics (e.g. pimozide, amisulpride, sertindole or phenothiazines), risperidone used to treat dementia
- medicines for high blood pressure or heart problems (uneven heart beat) such as calcium channel blockers, beta blockers, clonidine, moxonidine, sodium nitroprusside, amiodarone, disopyramide, flecainide, minoxidil, lidocaine, prazosin, diazoxide, methyl dopa, sotalol and mexiletine
- cardiac glycosides (drugs used to improve heart function) e.g. digoxin which is used to treat heart failure. Your doctor may need to change the dose of your medicine
- thymoxamine or hydralazine used to lower blood pressure
- metolazone- medicine used to pass more urine
- aliskiren - used to treat high blood pressure
- nitrates- used to lower blood pressure
- Lithium- used for mental illness
- Sucralfate- this drug may decrease the absorption of furosemide
- NSAIDs- drugs used to treat pain and inflammation (e.g. indomethacin, ketorolac)
- salicylates (e.g. aspirin)
- antibiotics belonging to class of aminoglycosides, polymyxins or vancomycin; as there may be a risk of ear or kidney damage, low sodium levels with trimethoprim, and cephalosporins e.g. cefalexin and ceftriaxone
- medicines used to treat depression (e.g. tricyclic antidepressants or monoamine oxidase inhibitors)
- medicines used to treat diabetes
- medicines used to treat epilepsy (e.g. carbamazepine, phenytoin)
- anti-histamines (medicines used to treat allergies)
- anti-fungals e.g. amphotericin (risk of potassium loss or renal damage indicated with furosemide)
- anti-virals e.g. nelfinavir, ritonavir or saquinavir
- choral hydrate or triclofos (drugs used to treat anxiety)
- drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) like e.g. atomoxetine, amphetamines
- steroids (used to treat inflammation)
- liquorice; increased risk of loss of potassium with furosemide
- platinum containing compounds like cisplatin- used to treat cancers (increased risk of kidney damage with furosemide)
- methotrexate- increase chance of furosemide toxicity
- levodopa- used to treat parkinson's disease (increased risk of lowering of blood pressure with furosemide)
- medicines that modify immune system- (e.g. aldesleukin, tacrolimus or ciclosporin)
- medicines used as muscle relaxants like baclofen, tizanidine or curare like drugs)
- birth control Pills or oestrogen containing drugs may block the effect of furosemide when taken concurrently
- progesterone containing drugs (drospiridone) may lead to reduced blood potassium levels if taken with furosemide
- medicines such as alprostadil, used to treat erectile dysfunction (impotency)
- theophylline used for wheezing or difficulty in breathing
- probenecid used for treatment of gout
- medicines used as general anaesthetics to induce unconsciousness. If you are going to have an anaesthetic please ensure that the doctor or nurse knows you are taking furosemide
- laxatives- drugs used to relieve constipation e.g. bisacodyl, senna
- medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- medicines used to treat blocked noses, such as ephedrine and xylometazoline
- aminoglutethimide used to treat breast cancer.

Furosemide with alcohol

Avoid consumption of alcohol with Furosemide as it may lead to excessive lowering of blood pressure.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine. Furosemide passes through the placenta and hence should not be given during pregnancy unless doctor feels it extremely necessary. If it is given in cases of swelling or water retention, the growth of the baby must be regularly monitored.

Breast-feeding

Furosemide passes into the milk and may inhibit secretion of milk. Hence it should be avoided in breast-feeding women.

Driving and using machines

Furosemide may cause some patients to be less alert which could interfere with the ability to drive or to operate machines. If you notice that you are not as alert as usual, do not drive or operate machinery and ask your doctor for advice.

Important information about some of the ingredients of Furosemide

Furosemide contains:

- **ethanol** (alcohol) up to 442 mg per 5 ml dose, (equivalent to 10.6 ml of beer or 4.4 ml of wine). To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as alcoholics and patients with liver disease, or epilepsy.
- **liquid maltitol** (hydrogenated glucose syrup). If you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE FUROSEMIDE

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

- Only take Furosemide by mouth.
- It is best to take this medicine in the morning, or according to a schedule which will least affect your activities and sleep.

The recommended dose is:

Adults:	Usual starting dose is 4 ml daily. Your doctor will adjust the dose to suit you, and will advise whether to take daily or on alternate days. Take exactly what is prescribed for you by your doctor. The maximum daily dose is 150 ml.
Children:	Your doctor will advise you on the correct dose. The maximum daily dose is 4 ml per day.
Elderly:	Your doctor will advise you on the correct dose.

If you take more Furosemide than you should:

If you take more Furosemide than you should, your body will lose blood salts and water. Contact your doctor or local hospital accident and emergency department **immediately** and take this leaflet or the medication with you.

If you forget to take Furosemide:

If you have forgotten to take your medicine, take it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose in one morning to make up for a forgotten individual dose.

4. POSSIBLE SIDE EFFECTS

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

If any of the below mentioned side effects are observed please inform your doctor immediately

- **allergic reactions** such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, "acute generalised exanthematous pustulosis (AGEP)", DRESS, (acute febrile drug eruption) characterised by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots bleeding in the skin
- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back
- abnormal blood counts, severe changes in blood count and signs e.g. sore throat, mouth ulcers, fever, unexplained bruising or bleeding
- signs of kidney inflammation e.g. blood in the urine, pain in the lower back
- signs of metabolic acidosis: chest pain, irregular heartbeat, nausea, vomiting, weakness.

The other possible side effects are listed under headings of frequency, using the following categories:

Uncommon (may affect up to 1 in 10 people):

- blurred vision
- 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
- sensitivity to light (photosensitivity)
- feeling of tiredness
- dry mouth, thirst, disturbances of bowel like diarrhoea, constipation or vomiting
- feeling sick (nausea)
- raised blood levels of creatinine and urea
- deafness (sometimes irreversible).

Rare (may affect up to 1 in 1,000 people):

- abnormal blood count (white blood cell deficiency) accompanied by an 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
- acute kidney failure
- hearing disorders & 'ringing' in the ears. These disorders are usually temporary in nature
- inflammation of a blood vessel
- 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
- fever
- muscle aches
- inability to control urination
- if you have a urinary tract obstruction, increased urine production may occur or worsen
- if you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly
- minor mental disturbances

Very rare (may affect up to 1 in 10,000 people):

- 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

Frequency not known (frequency cannot be estimated from the available data):

- certain liver function disorders or increase in certain liver enzymes
- furosemide can cause an excessive depletion of bodily fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium)
- if you have a shortage of sodium (sodium deficiency) symptoms are confusion, muscle cramps, muscle weakness, loss of appetite, dizziness, drowsiness and vomiting
- if you have a shortage of potassium (potassium deficiency) symptoms are muscular weakness and the inability to contract one or more muscles (paralysis), vomiting, constipation, 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
- if you have a shortage of magnesium and calcium (magnesium and calcium deficiency) symptoms include increased irritability of the muscles and heart rhythm disturbances
- deposits of calcium salts in the kidneys or heart defects like patent ductus arteriosus have been reported in premature babies following treatment with furosemide
- during treatment with furosemide, the blood levels of some fats (cholesterol and triglyceride) may rise, but usually return to normal within 6 months
- 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
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- increased requirement of insulin in diabetic patients due to decreased glucose tolerance
- confusion, forgetfulness, mood changes or unusual movements in patients with liver disease
- increase in blood creatinine and urea levels (usually not permanent)
- aggravation of pre-existing metabolic alkalosis

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FUROSEMIDE

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not use Furosemide after the expiry date stated on the label. Do not use Furosemide after the bottle has been opened for more than three months. 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 substance** is Furosemide 50 mg/5 ml.
- the **other ingredients** are liquid maltitol (E965), ethanol, disodium hydrogen phosphate dodecahydrate, sodium hydroxide, citric acid monohydrate, cherry flavour (containing propylene glycol) and purified water. *See end of Section 2.*

What Furosemide looks like and contents of the pack

Furosemide 50 mg/5 ml Oral Solution is a clear cherry flavoured liquid and is available in 150 ml amber glass bottles.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0074

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