

Package leaflet: Information for the user
Furosemide 20mg or 40mg Tablets
Furosemide

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it onto 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Furosemide 20mg or 40mg Tablets. In the rest of this leaflet it is called Furosemide Tablets.

What is in this leaflet:

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

1. What Furosemide Tablets are and what they are used for

Furosemide belongs to group of medicines called "diuretics". Diuretics make you pass more water (urine).

Excess fluid can build up in certain conditions which affect the heart, lungs, kidneys or liver. Furosemide Tablets are used to remove that fluid by making you pass more water.

They may also be used when your kidneys are not functioning properly and not producing normal amounts of urine, or to treat high blood pressure, alone or in combination with other medicines.

2. What you need to know before you take Furosemide Tablets

Do not take Furosemide Tablets 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
- you are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or cotrimoxazole
- you have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
- you have too little potassium or sodium in your blood (shown in blood test)
- you have severe liver problems (cirrhosis)
- you have already taken Furosemide in the past to treat failure to pass urine or kidney failure or if you have 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
- 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

- you have an illness called 'Addison's Disease'. This can make you feel tired and weak or if you are taking digoxin, used to treat heart problems
- you have a disease called porphyria characterized by abdominal pain, vomiting or muscle weakness
- you are breast feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Furosemide Tablets if:

- you are elderly, if you are on other medications which can cause a drop in blood pressure and if you have other medical conditions that are risks for a drop in blood pressure
- you have low blood pressure or feel dizzy when you stand up
- 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
- 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
- you are taking digoxin, used to treat heart problems
- you are taking any other water tablets
- you are going to have a glucose test
- you are going to give this to a baby that was born too early.

Do not take Furosemide Tablets if:

- you are planning to undergo procedure that includes the use of radiocontrast (as taking furosemide with this may increase the risk for kidney damage)
- you cannot tolerate certain sugars like galactose or glucose.

Take special precaution if:

- you are an elderly patient
- you have difficulty in passing water, for example because of an enlarged prostate gland (males only)
- you have diabetes
- you have gout (characterised by painful joints due to elevated uric acid levels)
- you have kidney or liver problems
- you have Addisons disease (inadequate functioning of the Adrenal gland)
- you have low blood protein levels as this may reduce the effect of the drug and increase the risk of ear damage
- you have raised levels of calcium in the blood; careful monitoring of fluids and electrolyte levels are recommended
- you have a risk of fall in blood pressure; or in case of premature infants as they may be more prone to development of kidney stones
- 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), liver damage or any symptom that may occur particularly to you
- you are an elderly patient with dementia and are also taking risperidone.

Other medicines and Furosemide tablets

Do not take this medicine and tell your doctor, if you are taking:

Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics) such as triamterene.

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

- 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 glycosides 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'). Your doctor may need to change the dose of your tablets or ask you to stop taking them
- medicines such as tricyclic antidepressants, hypnotics and anxiolytics (e.g. barbiturates)
- 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
- digoxin 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
- 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 (eg. Indomethacin, Ketorolac)
- salicylates (eg. aspirin)
- antibiotics belonging to class of aminoglycosides, polymyxins or vancomycin; as there may be a risk of ear or kidney damage.
- medicines used to treat depression (eg. TCA or MAOIs)
- medicines used to treat epilepsy (eg. Carbamazepine, Phenytoin)
- anti-histamines (medicines used to treat allergies)
- anti-fungals (risk of potassium loss or renal damage indicated with Furosemide)
- chloral hydrate or Trichlorfos (drugs used to treat anxiety)
- drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) like amphetamines
- steroids (used to treat inflammation)
- liquorice; increased risk of loss of potassium with Furosemide
- 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- (eg. Aldesleukin 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 if 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
- laxatives- drugs used to relieve constipation
- aminoglutethimide used to treat breast cancer
- medicines for diabetes. These may not work as well when you are taking Furosemide Tablets
- medicines used for mental problems called 'psychoses', such as risperidone, amisulpride, sertindole, pimozide and chlorpromazine. Avoid using pimozide at the same time as furosemide
- medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine
- medicines used as injections before x-ray examinations (radiocontrast agent).

Furosemide Tablets with alcohol

Avoid alcohol when taking Furosemide Tablets 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 your doctor feels it is 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 their ability to drive or 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.

Furosemide Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Furosemide Tablets

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

Unless told otherwise, take your tablets with water.

Adults including elderly

- The usual starting dose for excess fluid is 40mg in the morning which may be reduced to 20mg daily or 40mg every other day
- The dose may be increased if necessary to 80mg or more as one or two doses daily or every other day.
- The usual starting dose to improve urine production is 250mg daily.
- This may be increased if necessary, in steps of 250mg, to larger doses given every four to six hours.
- The usual dose for high blood pressure is 40-80mg daily. If you are taking these tablets for high blood pressure, your doctor may also prescribe another drug for high blood pressure, to be taken together with your furosemide treatment.

Use in children

- For children, the usual dose is 1 to 3mg per kg bodyweight daily up to a maximum of 40mg daily.

You will find that you have the urge to pass water soon after taking your medicine. Because of this it is better to take your tablet(s) first thing in the morning, so that you pass any extra water early in the day. This will leave you free to go about your usual routine, undisturbed. If you work at night, it may be better for you to take your tablet(s) in the evening.

Whilst you are receiving treatment with this medicine, your doctor may want to take blood for testing which will show if you have the right balance of fluid and chemicals in the body.

If you take more Furosemide Tablets than you should

If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take your Furosemide Tablets with you. Taking too much Furosemide Tablets may make you feel confused, unable to focus, show a lack emotion or interest in anything. You may also have dizziness, light headedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of body that is affected). You may also have problems with your kidneys or blood.

If you forget to take Furosemide Tablets

If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take more than one dose at a time.

If you stop taking Furosemide Tablets

Speak to your doctor before you stop taking Furosemide Tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to hospital straight away:

- 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)"

(acute febrile drug eruption) characterized by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin

- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back
- any unexplained bruising or bleeding, fever, sore throat, mouth ulcers. This could be a sign of low blood counts, agranulocytosis
- signs of kidney inflammation e.g. pain in sides, blood in urine.

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

Uncommon (may affect up to 1 in 100 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
- 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.

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). 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 with an urge to vomit, or diarrhoea
- metabolic acidosis characterized by chest pain, irregular heart beat, headache, feeling sick, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone pain and joint pain.
- if you have a shortage of sodium (sodium deficiency):
 - cramp in the calf muscles
 - loss of appetite
 - listlessness
 - feeling of weakness
 - dizziness
 - drowsiness
 - confusion.
- if you have a shortage of potassium (potassium deficiency):
 - 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.
- if you have a shortage of magnesium and calcium (magnesium and calcium deficiency):
 - increased irritability of the muscles
 - 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original container in which the tablets were given to you in order to protect from light. Do not transfer your tablets to another container.
- Do not use after the expiry date stated on the carton and the bottle. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Furosemide Tablets contain

- The active substance is furosemide
- The tablets come in two strengths, 20mg and 40mg.
- The other ingredients are lactose, maize starch, pre-gelatinised maize starch and magnesium stearate.

What Furosemide Tablets look like and contents of the pack

Furosemide 20mg Tablets are white, circular, flat tablets with a breakline and F20 on one side and CP on the other.

Furosemide 40mg Tablets are white, circular, flat tablets with a breakline and F40 on one side and CP on the other.

Furosemide Tablets are available in strip packs of 28 tablets

Marketing Authorisation Holder

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Manufacturer

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	Reference number
Furosemide 20mg Tablets	PL 53797/0077
Furosemide 40mg Tablets	PL 53797/0078

This is a service provided by the Royal National Institute of Blind People.

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