

Package Leaflet: Information for patient

Furosemide 20mg Tablets BP

The product name Furosemide 20mg Tablets BP is referred as Furosemide Tablets in the leaflet.

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, please ask your doctor or pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Furosemide belongs to a group of drugs called diuretics. Water, sodium, potassium and waste products are filtered out of the bloodstream in the kidney. Most of the water and filtered salts are subsequently reabsorbed by the bloodstream. Furosemide blocks the movement of sodium back into the bloodstream, thereby preventing the re-absorption of water, causing you to pass more urine than you usually do.

Furosemide is used to treat oedema (fluid retention) caused by heart failure, and certain liver and kidney disorders blood vessels or high blood pressure problems. It is also used to manage a condition called oliguria, where the body produces abnormally small amount of urine, due to kidney disease.

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.
- are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or cotrimoxazole
- have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
- have too little potassium or sodium in your blood (shown in blood test)
- have severe liver problems (cirrhosis)
- 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
- 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 ok to have this medicine. Your doctor will be able to decide.
- 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.

- have digitalis poisoning (feeling or being sick, high levels of potassium in the blood, slow, fast or irregular heart beats)
- have a rare condition called porphyria characterised by abdominal pain, vomiting or muscle weakness
- Take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. Amiloride or Spironolactone)
- are breast-feeding
- Furosemide Tablets are not recommended in children and adolescents below 18 years of age.

Warnings and precautions

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

- are elderly, if you are on the other medications which can cause the drop in the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- have low blood pressure or feel dizzy when you stand up
- 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.
- have low blood levels of essential minerals like sodium or potassium or you have acid base imbalance in the body identified by blood tests
- are taking digoxin, used to treat heart problems
- are taking any other water tablets
- are going to have a glucose test
- 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, this may increase the risk of kidney damage)

Take special precaution if you:

- have difficulty in passing water, for example because of an enlarged prostate gland (males only)
- have diabetes
- have gout (characterised by painful joints due to elevated uric acid levels)
- have kidney or liver problems
- have adrenal disease
- have Addison's disease (inadequate functioning of the Adrenal gland)
- have low blood protein levels as this may reduce the effect of the drug and increase the risk of ear damage
- have raised levels of calcium in the blood, careful monitoring of fluids and electrolyte levels are recommended
- 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
- are already on medicines like NSAIDs (used for inflammation and pain) or ACE inhibitors (medicines used to lower blood pressure)
- are elderly patient with dementia and are also taking risperidone
- laboratory monitoring- it is recommended to undergo regular monitoring of blood levels of 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.

Your doctor may monitor you and may take blood for testing while you are taking this medicine.

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, methyldopa, sotalol, tocainide and mexiletine
- 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
- 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 at risk of ear or kidney damage
- antibiotics such as trimethoprim and cephalosporins
- medicines used to treat depression (e.g. TCA or MAOIs)
- medicines used to treat epilepsy (e.g. carbamazepine, phenytoin)
- anti-histamines (medicines used to treat allergies)
- anti-fungals such as amphotericin (risk of potassium loss or renal damage indicated with furosemide)
- chloral hydrate or triclofos (drugs used to treat anxiety)
- drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) like amphetamine
- Steroids (used to treat inflammation) and any corticosteroids
- Liquorice; increased risk of loss of potassium with furosemide
- cisplatin-used to treat cancers (increased risk of kidney damage with furosemide)
- methotrexate – increased chance of furosemide toxicity
- levodopa-used to treat Parkinson's disease (increased risk of lowering 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 if taken concurrently

- progesterone containing drugs (drospiridone) may lead to increased 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, phenothiazine 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 doses of your medicine
- medicines used as injections before X-ray examinations (radiocontrast agent).
- Carbenoxolone - used to treat ulceration and inflammation

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or planning to have a baby, ask your doctor or nurse for advise before taking this medicine.

Pregnancy:

Furosemide passes through the placenta and hence should not be given during pregnancy unless your 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:

Do not breast-feed if you are taking Furosemide Tablets. This is because small amounts may pass into the mother’s milk and may inhibit secretion of milk.

Furosemide Tablets with food, drink and alcohol

You should avoid drinking alcohol while taking Furosemide Tablets as this may lower your blood pressure further.

Driving and using machines

Do not drive or operate machinery if you feel less alert, dizzy or have blurred vision after taking Furosemide Tablets

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 medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

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.

Adults and children over 12 years

Water retention: The usual starting dose is 40 mg in the morning, then 20 mg daily or 40 mg on alternate days. Up to 80 mg a day may be given. High blood pressure: 20-40 mg twice a day.

Elderly: You may be given a lower dose to start.

If necessary, your doctor may adjust the dose to suit your individual requirements. You should NOT adjust the dose unless instructed to do so by your doctor.

Children under 12 years

Your doctor will tell you the exact dose for your child based on your child's weight. The usual dose is between 1 to 3 mg per kilogram of your child's body weight.

The maximum dose for children is 40 mg daily.

Dose adjustment may be required

Your doctor may adjust your dosage if you have a low level of protein in the blood (hypoproteinaemia) or problems with your liver.

How to take your tablets

You should take your tablets in the morning, unless instructed otherwise by your doctor. Swallow the tablets with a drink of water.

If you take more Furosemide Tablets than you should

This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you. Taking too many Furosemide Tablets may make you feel confused, unable to focus, show a lack of emotion or interest in anything. You may also have dizziness, lightheadedness, 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 have forgotten to take a dose, leave out that dose completely. Take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose. If you have trouble remembering to take your tablets, tell your doctor or pharmacist.

If you stop taking Furosemide Tablets:

Keep taking Furosemide Tablets until your doctor tells you to stop. Do not stop taking Furosemide Tablets just because you feel better.

If you have any further questions on the use of Furosemide Tablets ask your doctor or pharmacist.

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)" (acute febrile drug eruption) characterised 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. Rarely could also lead to acute kidney failure.

- metabolic acidosis characterised by chest pain, irregular heart beat, headache, feeling sick, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone pain and joint pain
- certain liver function disorders or increase in certain liver enzymes - a life-threatening form of unconsciousness
- 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.

Tell your doctor or pharmacist if you notice any of the following side effects:

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)
- 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).
- Irregular heart rate.

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
- hearing disorders & ringing in the ears.
These disorders are usually temporary in nature.
- inflammation of a blood vessel
- fever
- Shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilation of the blood vessels due to allergy to certain substances
- muscle aches
- inability to control urination
- if you have a urinary tract obstruction, increased urine production may occur or worsen
- Increased urine production may occur or worsen if you have a urinary tract infection
- 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.

- if you have a shortage of sodium deficiency)
- Metabolic acidosis characterized by chest pain, irregular heart beat, headache, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone pain and joint pain
- 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
- changes in glucose test (bullet point)
- 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)

Additional side effects in children

- Increased risk or persistence of patent ductus arteriosus in premature infants
- Kidney stones in premature babies

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 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 Tablets

Keep this medicine out of the sight and reach of children. Keep in the original packaging.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Tablets contain:

The active substance in this medicine is called furosemide. The 20 mg tablets contain 20 mg furosemide.

The other ingredients are Lactose monohydrate, magnesium stearate, sodium starch glycollate and maize starch.

What do your tablets look like and contents of the pack:

Furosemide 20mg Tablets BP are white, circular tablets, flat tablets with a break line on one side. Each tablet contains furosemide 20 mg.

Pack sizes: 20mg tablets- 28, 56,100, 250, 500 and 1000 tablets in polypropylene container with low density polyethylene cap.

28 and 56 tablets in PVC/ Al Blisters packs.

Not all pack sizes may be marketed.

Who has made your tablets:

Strada Production Ireland Ltd, Waterford Road, Clonmel, Co.Tipperary.

Product Licence Holder:

Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, WA8 0RP, UK.

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