Package Leaflet: Information for the patient

Furosetic 40 mg

Scored 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 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 Furosetic is and what is it used for

Pharmacotherapeutic group

Furosetic is a diuretic (a medicine that promotes urine production).

Therapeutic indications

Furosetic is used in the following cases:
- Fluid accumulation in tissue (edema) following heart or liver disease,
- Fluid accumulation in tissue (edema) following kidney disease (if you have nephrotic syndrome, which involves protein loss, lipid metabolism disorders and water accumulation, treatment of the underlying disease is the most important),
- Fluid accumulation in tissue (edema) following burns,
- High blood pressure (hypertension).

2. What you need to know before you take Furosetic

Contraindications

Furosetic must not be taken:
- If you are allergic to furosemide, sulfonamides (possible cross-allergy with furosemide) or any other ingredient in Furosetic tablets listed in Section 6,
- If you have kidney failure with no urine production (anuria), which – does not respond to Furosetic treatment,
- If you have liver failure with consciousness disorders (coma and hepatic precoma),
- If you have a severe potassium deficiency,
- If you have a severe sodium deficiency,
- If you have a blood volume deficit (hypovolemia) or body water deficit (dehydration),
- If you are breast-feeding (see "Pregnancy and breast-feeding').

Warnings and Precautions

Talk to your doctor or pharmacist before taking Furosetic:
- If your blood pressure is very low,
- If you have already existing (established) or underlying (latent) diabetes mellitus; regular monitoring of blood sugar levels is required,
- If you have gout; regular monitoring of blood uric acid levels is required,
- If you have difficulty passing urine (e.g. due to enlarged prostate, obstruction of the kidney, or shrinking of the tube that runs from the kidney to the bladder),
- If your blood protein level is decreased, e.g. in nephrotic syndrome (which is characterized by protein loss, lipid metabolism disorders and water accumulation); dosage must be carefully adjusted,
- If you have rapidly progressive kidney dysfunction in connection with a serious liver disease such as liver cirrhosis (hepatorenal syndrome),
- If you have blood flow disorders in the brain vessels or heart vessels, since you would be particularly at risk if you experienced a sharp adverse drop in blood pressure.

In patients with urination disorders (e.g. due to enlarged prostate), Furosetic may only be taken if normal urine output can be restored, since a sudden flow of urine could result in obstruction (retention of urine), which could strain the bladder.
Furosetic increases excretion of sodium and chloride, and consequently water.
Excretion of other electrolytes (especially potassium, calcium and magnesium) is also increased. Since water/electrolyte balance disorders have often been observed during treatment with Furosetic due to higher levels of water and electrolyte excretion, regular checks of the levels of certain substances in the blood are required.
Especially during long-term treatment with Furosetic, certain blood tests, particularly potassium, sodium, calcium, bicarbonate, creatinine, urea, and uric acid, as well as blood glucose, should be regularly performed.
Particularly careful monitoring is required if you are at high risk for electrolyte disturbances, or if you have severe fluid loss (e.g. due to vomiting, diarrhea, or excessive sweating). Any deficit in circulating blood volume, body water deficit, significant electrolyte disturbances, or acid-base balance disturbances must be corrected. This may require temporary adjustment of Furosetic treatment.
Underlying diseases (e.g. liver cirrhosis, cardiac insufficiency), concomitant medication and food can play a role in the possible development of electrolyte disorders.
Weight loss due to increased urine excretion should not exceed 1 kg/day, regardless of how much urine is passed.
If you have nephrotic syndrome (see above), particularly strict compliance with the prescribed dose is essential, due to the increased risk of side effects.
Use of furosemide (the active substance in Furosetic) in combination with risperidone:
In placebo-controlled studies with risperidone in elderly patients with dementia, a higher mortality rate was observed in patients who were treated simultaneously with furosemide and risperidone as compared with those who received risperidone or furosemide alone. Caution is therefore necessary, and the benefits and risks of using this combination or of simultaneous treatment with other potent diuretics should be carefully weighed by your doctor. Loss of body water should be avoided.

Children

Particularly careful monitoring is required in premature infants, since they are at risk for renal calcification or kidney stones. Monitoring methods include kidney function tests and ultrasounds.
In premature infants with condition involving difficulty breathing (respiratory distress syndrome) who are given diuretic treatment with Furosetic in the first weeks of life, there may be a higher risk that the vessel that shunts pulmonary circulation before birth will remain open (patent ductus arteriosus).

Effects of improper use for doping purposes

Use of Furosetic may yield positive results in doping tests. In addition, use of Furosetic as doping substance can be dangerous for your health.

Other medicines and Furosetic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
The efficacy of Furosetic may be affected by simultaneous treatment with the following drugs or groups of medicines:
- Glucocorticoids (cortisone), carbenoxolone or laxatives, as they may increase potassium loss, which can result in potassium deficiency.
- Medicines with an anti-inflammatory effect (nonsteroidal anti-inflammatory drugs, such as indomethacin and aspirin), as they may reduce the effect of Furosetic. If Furosetic treatment results in a decrease in circulating blood volume or a body water deficit, simultaneous use of nonsteroidal anti-inflammatory drugs may cause acute kidney failure.
- Probenecid (antigout agent), methotrexate (antirheumatic agent and immunosuppressant) and other drugs which, like furosemide, are excreted in the urine, as they may reduce the effect of Furosetic.
- Phenytoin (a drug used to treat seizures and certain types of pain), as it has been reported to reduce the effect of Furosetic.
- Sucralfate (a stomach drug), as it reduces the amount of Furosetic absorbed in the intestine and thereby decreases its effect. An interval of at least two hours should be allowed between use of the two drugs.

The effectiveness of the following drugs or groups of medicines may be affected by simultaneous treatment with Furosetic.
- Certain cardiac agents (glycosides), as the sensitivity of the heart muscle to these drugs may increase if a potassium or magnesium deficiency develops during treatment with Furosetic. There is a higher risk of heart rate disorders (ventricular arrhythmias, including torsades de pointes) in patients with electrolyte imbalances and when Furosetic is used together with drugs that can cause certain ECG changes (prolongation of QT interval) (e.g. terfenadine, an antiallergic, and certain medicines used in heart rate disorders [class I and III antiarrhythmics]).
- Salicylates (painkillers) used at high doses, as their side effects may be enhanced by simultaneous use with Furosetic.
- Medicines that damage the kidneys (nephrotoxic drugs) (e.g. antibiotics such as aminoglycosides, cephalosporins, polymyxins), as Furosetic may enhance their harmful effects. Kidney function may deteriorate in patients receiving both Furosetic and high doses of certain cephalosporins.
- Aminoglycosides (e.g. kanamycin, gentamicin, tobramycin) and other medicines that damage hearing (ototoxic drugs), as their effects may be increased by simultaneous use of Furosetic. Hearing impairment may not be reversible. Consequently, simultaneous use of the drugs mentioned above should be avoided.
- Cisplatin (treatment for cancer), as simultaneous use with Furosetic may result in hearing impairment. In addition, Furosetic must be used with extra caution since it may enhance the harmful effects of cisplatin on the kidneys (nephrotoxicity).
- Lithium (used in certain forms of depression), as simultaneous use of Furosetic may enhance the harmful effects of lithium on the heart (cardiotoxicity) and nerves (neurotoxicity). The blood lithium level should therefore be closely monitored in patients receiving these two drugs simultaneously.
- Medicines for high blood pressure (antihypertensives), diuretic drugs, or other drugs that may lower blood pressure, as, if they are used at the same time as Furosetic, blood pressure may decrease even more.

Major drops in blood pressure leading to shock, and a deterioration of kidney function (with isolated cases of acute kidney failure) have been observed, particularly when using ACE inhibitors or angiotensin II receptor antagonists for the first time or introducing higher doses of these drugs. If possible, Furosetic treatment should therefore be stopped temporarily, or at least the dose should be reduced to three days, before treatment with an ACE inhibitor or angiotensin II receptor antagonist is started or the dose increased.
- Probenecid, methotrexate, and other drugs which, like furosemide, are excreted via the kidneys, as Furosetic may reduce the elimination of these drugs. High-dose treatment may result in higher levels of active substances in the blood and increase the risk of side effects.
- Theophylline (antiasthmatic drug) or curare-like agents that cause muscle relaxation (muscle relaxants), as their effects may be enhanced by Furosetic.
- Drugs that lower blood sugar levels (antidiabetics) or increase blood pressure (sympathomimetic drugs, e.g. adrenalin, noradrenalin), as their effects may be reduced by simultaneous use of Furosetic.
- Risperidone: caution is necessary in patients treated with risperidone, and the benefits and risks of using this combination or of simultaneous treatment with Furosetic or other potent diuretics should be carefully weighed by your doctor.

Other interactions:
- Simultaneous use of cyclosporine A and Furosetic is linked to a higher risk of arthritis due to gout, as a result of increased blood uric acid levels caused by furosemide and impaired urine excretion of uric acid caused by cyclosporine.
- In people who are at high risk for kidney impairment during x-rays with constant agents, kidney function deteriorated after the examination using contrast agents more frequently in patients treated with Furosetic than in those who only received intravenous fluids before the examination with contrast agents.
- In isolated cases, intravenous use of Furosetic within 24 hours of taking chloral hydrate resulted in sensations of warmth, sweating, agitation, nausea, and increased blood pressure and heart rate (tachycardia). Consequently, simultaneous use of Furosetic and chloral hydrate should be avoided.

Using with food and drink

Eating large quantities of licorice under treatment with Furosetic may increase potassium loss.

Pregnancy and Breast-feeding

Do not use Furosetic during pregnancy unless your doctor considers it absolutely necessary, since the active substance furosemide passes into the placenta.
Furosemide passes into breast milk and reduces the amount of milk produced. Consequently, you should not be treated with Furosetic if you are breast-feeding. If necessary, you must stop breast-feeding.

Driving and using machines

Even when this medicine is used as specified, it may affect your capacity to react to such an extent that it may impair your ability to drive, use machines, or work in areas of uneven footing. This applies even more at the beginning of treatment, when increasing doses, when switching drugs, and in combination with alcohol.

Important information about some of the ingredients of Furosetic

This medicine contains lactose.
Talk to your doctor before taking Furosetic, if you know that you have an intolerance to certain sugars.

3. How to take Furosetic

Always use Furosetic exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Dosage should be determined on a case-by-case basis and, above all, depending on how you respond to the treatment. The lowest dose that achieves the desired effect should always be used.
Unless otherwise prescribed, the following dosages are recommended for adults:
For fluid accumulation in tissue (edema) following heart or liver disease:
The usual starting dose for adults is 40 mg of furosemide, equivalent to 1 x Furosetic 40 mg tablet. If urine output remains insufficient, the unit dose may be doubled after six hours to 80 mg of furosemide, equivalent to 2 x Furosetic 40 mg tablets. If urine output still does not improve after this dosage increase, after another six hours 4 x Furosetic 40 mg tablets (equivalent to 160 mg of furosemide) may be taken.
The daily maintenance dose is generally 40 mg to 80 mg of furosemide, equivalent to 1 to 2 x Furosetic 40 mg tablets.
Body weight loss caused by increased urine excretion should not exceed 1 kg/day.
For fluid accumulation in tissue (edema) following kidney disease:
The usual starting dose for adults is 40 mg of furosemide, equivalent to 1 x Furosetic 40 mg tablet. If urine output remains insufficient, the unit dose may be doubled after six hours to 80 mg of furosemide, equivalent to 2 x Furosetic 40 mg tablets. If urine output still does not improve after this dosage increase, after another six hours 4 x Furosetic 40 mg tablets (equivalent to 160 mg of furosemide) may be taken.
The daily maintenance dose is generally 40 mg to 80 mg of furosemide, equivalent to 1 to 2 x Furosetic 40 mg tablets.
Body weight loss caused by increased urine excretion should not exceed 1 kg/day.
If you have nephrotic syndrome, the dose must be carefully determined, due to the increased risk of side effects.
For fluid accumulation in tissue (edema) following burns:
The daily and/or unit dose ranges from 40 mg to 100 mg of furosemide, equivalent to 1 to 2½ x Furosetic 40 mg tablets. In exceptional cases, in patients with impaired kidney function, the dose may be up to 240 mg of furosemide, equivalent to 6 x Furosetic 40 mg tablets.
Any blood volume deficit must be corrected before using Furosetic.
For high blood pressure (hypertension):
In general, take 1 x Furosetic 40 mg tablet daily (equivalent to 40 mg of furosemide) alone or in combination with other medicines.
Children:
The dosage for children is usually 1 mg (to 2 mg) of furosemide per kilogram of body weight per day. However, the dosage for children must not exceed 40 mg of furosemide per day.

Method and duration of treatment

Swallow the tablets whole on an empty stomach in the morning with enough liquid (e.g. a glass of water).
Your doctor decides on the duration of treatment. This is based on the type and severity of the disease.

If you take more Furosetic than you should

If you suspect an overdose, because you have taken more Furosetic than you should have, alert a doctor immediately. The doctor can decide on the measures that may be necessary, depending on the severity of the overdose.
The signs of acute or chronic overdose depend on the severity of the salt and fluid losses.
Overdose may result in low blood pressure and blood circulation disorders when standing up from a lying position, electrolyte imbalances (decreased potassium, sodium, and chloride levels) and increased blood pH (alkalosis).
More severe fluid loss may result in body water deficit and, due to blood volume losses, in circulatory shock and thickening of the blood (hemoconcentration) with a tendency for thrombosis (blood clots).
Sudden water and electrolyte losses can result in confusion.

If you forget to take Furosetic

If you forget to take Furosetic, do not take twice the amount, but continue taking the prescribed dose.

If you stop taking Furosetic

Do not stop taking Furosetic or end your Furosetic treatment prematurely unless your doctor tells you to, because this can have an effect on the success of your treatment.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Blood
Common (1 to 10 people in 100): thickening of the blood (hemoconcentration, in case of excessive urine excretion).
Uncommon (1 to 10 people in 1,000): decrease in the number of certain blood cells called platelets (thrombocytopenia).
Rare (1 to 10 people in 10,000): increase in the number of certain white blood cells (eosinophilia), decrease in the overall number of white blood cells (leukopenia).
Very rare (Fewer than 1 person in 10,000): anemia due to increased destruction of red blood cells (hemolytic anemia), anemia due to blood cell formation disorders in the bone marrow (aplastic anemia), severe decrease in certain white blood cells with increased susceptibility to infections and poor general health (agranulocytosis).
Signs of agranulocytosis can include fever with shivering, changes to the mucous membrane (the lining of certain organs or cavities) and sore throat.
Immune system
Uncommon (1 to 10 people in 1,000): allergic reactions of the skin and mucous membranes (see 'Skin').
Rare (1 to 10 people in 10,000): severe allergic reactions such as circulatory shock (anaphylactic shock). The first signs of shock include skin reactions such as severe flushing or hives, agitation, headache, bouts of sweating, nausea, and bluish discoloration of the skin.
Metabolism and nutrition
(See 'Appropriate precautions for use; special warnings')
Very common (More than 1 person in 10): electrolyte imbalances (including those involving symptoms), reduced body water and reduced circulating blood volume (particularly in older patients), increase in certain blood fats (triglycerides).
Common (1 to 10 people in 100): reduced sodium and chloride levels in the blood (hyponatremia and hypochloremia, especially if sodium chloride intake is reduced), lower potassium levels in the blood (hypokalemia, especially with a simultaneous decrease in potassium supply and/or increased potassium loss, e.g. due to vomiting or chronic diarrhea); increased blood cholesterol, increased uric acid in the blood, and attacks of gout.
Uncommon (1 to 10 people in 1,000): increased blood sugar levels (reduced glucose tolerance, hyperglycemia), in patients with existing diabetes (established diabetes mellitus), this may lead to deterioration of patient metabolism.
Underlying diabetes (latent diabetes mellitus) may be revealed.
Incidence unknown (Cannot be estimated based on available data): reduced calcium levels in the blood (hypocalcemia), reduced magnesium levels in the blood (hypomagnesemia), increase in pH value of the blood (metabolic alkalosis), Pseudo-Bartter's syndrome (i.e. kidney function impairment induced by incorrect use of furosemide or long-term furosemide treatment, characterized by increase in blood pH value, loss of mineral salts and hypotension).
Symptoms that are often reported with sodium deficiency include apathy, calf cramps, loss of appetite, weakness, drowsiness, vomiting and convulsion.
Potassium deficiency may lead to symptoms such as muscle weakness, abnormal sensations in the hands and feet (e.g. tingling, numb or painful burning sensations), paralysis, vomiting, constipation, build-up of excessive gas to the digestive tract, excessive urine output, abnormal feeling of thirst with excessive fluid intake and irregular pulse (e.g. excitation and conduction disorders of the heart). Severe potassium loss may result in intestinal paralysis (paralytic ileus) or consciousness disorders and even coma.
Calcium deficiency may, in rare cases, result in neuromuscular hyperexcitability (tetany).
As a result of magnesium deficiency, tetany and heart rate disorders have been reported in rare cases.
Nervous system
Common (1 to 10 people in 100): brain disease (hepatic encephalopathy) may occur in patients with advanced liver failure.
Rare (1 to people in 10,000): tingling, numb or painful burning sensations in the hands and feet (paresthesia).
Ears
Uncommon (1 to 10 people in 1,000): hearing disorders, usually reversible, especially in patients with kidney function disorders or decreased blood protein levels (e.g. in nephrotic syndrome) and/or if the medicine is injected too quickly into the vein. Deafness, in some cases lasting for a while, has been reported after oral and intravenous use of the medicine.
Rare (1 to 10 people in 10,000): ringing of the ears (tinnitus).
Blood vessels/circulation
Very common (More than 1 person in 10) (with intravenous infusions): reduced blood pressure, including circulation disorders when standing up from a lying position.
Rare (1 to 10 people in 10,000): blood vessel inflammation (vasculitis)
Incidence unknown (Cannot be estimated based on available data): blockage of blood vessels due to a clot (thrombosis, particularly in older patients).
Excessive urine output may be accompanied by circulation disorders (even circulatory collapse), especially in older patients and children, resulting in particular in headache, dizziness, sight disorders, dry mouth, thirst, low blood pressure and circulation disorders with a drop in blood pressure when standing up from a lying position.
Digestive tract
Uncommon (1 to 10 people in 1,000): nausea.
Rare (1 to 10 people in 10,000): vomiting, diarrhea.
Very rare (Less than 1 person in 10 000): acute inflammation of the pancreas.
Liver and gall bladder
Very rare (Less than 1 person in 10,000): obstruction of bile flow (intrahepatic cholestasis), increase in certain liver values (transaminases).
Skin
Uncommon (1 to 10 people in 1,000): itching, hives (urticaria), rash, reactions of the skin and mucous membranes with redness, formation of blisters or scales (e.g. bullous dermatitis, erythema multiforme, pemphigoid, exfoliative dermatitis, purpura), increased sensitivity to light (photosensitivity).
Incidence unknown (Cannot be estimated based on available data): severe skin and mucous membrane reactions, for example with blisters or skin detachment (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, drug eruption with eosinophilia and systemic symptoms).
Kidneys and urinary tract
Very common (More than 1 person in 10): increased blood creatinine.
Common (1 to 10 people in 100): increased urine output.
Rare (1 to 10 people in 10,000): kidney inflammation (tubule-interstitial nephritis).
Incidence unknown (Cannot be estimated based on available data): increased sodium in urine, increased chloride in urine, increased urea in blood, signs of impaired urine excretion (e.g. in patients with an enlarged prostate, build-up of urine in the kidneys, narrowed ureter). This can even lead to urinary obstruction (urinary retention) and the resulting complications (see 'Warnings and Precautions'), kidney stones and/or calcification of kidney tissue in premature babies, kidney failure (see 'Other medicines and Furosetic').
Congenital diseases
Incidence unknown (Cannot be estimated based on available data): increased risk of the vessel that shunts pulmonary circulation before birth remaining open (patent ductus arteriosus), if premature babies are treated with furosemide in the first weeks of life.
Effect on overall state of health
Rare (1 to 10 people in 10,000): fever.
If a side effect occurs suddenly or becomes more severe, inform your doctor immediately, since some drug reactions may become life-threatening in certain circumstances. The doctor will decide what measures must be taken and whether the therapy can be continued.
At the first sign of an allergic reaction, Furosetic should not be used again.
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.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Furosetic

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from light and humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Furosetic 40 mg tablets contain:

The active substance is furosemide. Each tablet contains 40 mg of furosemide.
The other ingredients are: Lactose monohydrate, Pregelatinized starch, Sodium starch glycolate, Colloidal anhydrous silica, Talc, Magnesium stearate.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

What Furosetic look like and contents of the pack

Furosetic 40 mg tablets are white round scored tablets.
Furosetic is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon
P.O. Box 90201 Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com

Reg. N° for Furosetic 40 mg in Lebanon: 27515/93

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

This leaflet was last revised in August 2021.

Rev. 09/2021 905389-A