

# Lasix<sup>®</sup> 40 mg

tablets

*Furosemide*

**sanofi aventis**

## In this leaflet:

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## 1. WHAT Lasix 40 mg tablets ARE AND WHAT THEY ARE TAKEN FOR

Lasix 40 mg tablets are a diuretic (a medicine that promotes urine production).

Lasix 40 mg tablets are taken

- for fluid accumulation in tissue (edema) due to heart or liver disease
- for fluid accumulation in tissue (edema) due to kidney disease (in nephritic syndrome, which involves protein loss, lipid metabolism disorders, and water accumulation, treatment for the underlying disease is the most important)
- for fluid accumulation in tissue (edema) due to burns,
- for high blood pressure (hypertension).

## 2. BEFORE YOU TAKE Lasix 40 mg tablets

**Lasix 40 mg tablets must not be taken**

- if you are hypersensitive (allergic) to furosemide, sulfonamides, or any other ingredient in Lasix 40 mg tablets,
- if you have acute kidney failure with no urine production (anuria),
- if you have acute liver failure with consciousness disorders (coma and hepatic precoma),
- if you have a severe potassium deficit,
- if you have a severe sodium deficit,
- if you have a blood volume deficit (hypovolemia) or body water deficit (dehydration),
- if you are breast-feeding (see also "Pregnancy and breast-feeding").

**Take special care with Lasix 40 mg tablets**

- if your blood pressure is very low (hypotension),
- if you have already existing or underlying 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 impaired urine excretion (e.g. enlarged prostate, intrarenal obstruction, ureteral stenosis),
- if your blood protein level is decreased (hypoproteinemia), e.g. in nephrotic syndrome (protein loss, lipid metabolism disorders, and water accumulation); dosage must be carefully adjusted,
- if you have liver cirrhosis as well as impaired kidney function,
- if you have blood flow disorders in the brain vessels (cerebrovascular perfusion disorders) or heart vessels (coronary disease), since you would be particularly at risk if you experienced a sharp adverse drop in blood pressure.

In patients with urination disorders (e.g. enlarged prostate), Lasix 40 mg tablets may only be taken if normal urine output can be restored, since a sudden onset of urine flow could result in obstructive anuria, which could strain the bladder.

During long-term treatment with Lasix, 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 (hypovolemia), body water deficit (dehydration), significant electrolyte disturbances, or acid-base balance disturbances must be corrected. This may require temporary adjustment of Lasix treatment.

Weight loss due to increased urine excretion should not exceed 1 kg/day regardless of the extent of urine output.

If you have nephrotic syndrome (see above), particularly strict compliance with the prescribed dose is essential, due to the increased risk of adverse effects.

Simultaneous administration 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 to those who received risperidone or furosemide alone. Caution is therefore recommended, 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 water (dehydration) 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 ultrasound. In premature infants with conditions involving difficulty breathing (respiratory distress syndrome) undergoing diuretic treatment with Lasix in the first weeks of life, there may be a higher risk that the vessel that shunts pulmonary circulation before birth will remain open (persistent patent ductus arteriosus).

## Effects of improper use for doping purposes

Use of Lasix 40 mg tablets may yield positive results in doping tests. In addition, use of the drug as a doping substance can be hazardous to your health.

## Taking/using other medicines

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including those obtained without a prescription. The efficacy of Lasix 40 mg tablets may be affected by simultaneous treatment with the following drugs or groups of medicines:

- Glucocorticoids (cortisone), carbenoxolone, or laxatives may increase potassium loss, which can result in potassium deficit.
- Medicines with an antiinflammatory effect (nonsteroidal antiinflammatory drugs, such as indomethacin and aspirin) may reduce the effect of Lasix. If Lasix treatment results in a decrease in circulating blood volume (hypovolemia) or body water deficit (dehydration), simultaneous administration of nonsteroidal antiinflammatory 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, may reduce the effect of Lasix.
- Simultaneous administration of phenytoin (drug used to treat seizures and certain types of pain) has been reported to reduce the effect of Lasix.
- Since sucralfate (stomach drug) reduces the intestinal absorption of Lasix and thereby decreases its effect, an interval of at least two hours should be allowed between administration of the two drugs.
- The effectiveness of the following drugs or groups of medicines may be affected by simultaneous treatment with Lasix 40 mg tablets.
- During simultaneous treatment with certain cardiac agents (glycosides), it should be noted that

the sensitivity of the heart muscle to these drugs may be increased by a potassium or magnesium deficit developing under treatment with Lasix. There is a higher risk of heart rate disturbances (ventricular arrhythmias, including torsades de pointes) during simultaneous administration of drugs (e.g. terfenadine, an anti-allergic, and certain medicines used in heart rate disturbances [class I and III antiarrhythmics]) that can cause certain ECG changes (prolongation of QT interval) and in patients with electrolyte disturbances.

- The adverse effects of high-dose salicylates (painkillers) may be enhanced by simultaneous use with Lasix.

- Lasix may enhance the harmful effects of medicines that damage the kidneys (nephrotoxic drugs) (e.g. antibiotics such as aminoglycosides, cephalosporins, polymyxins). Kidney function may deteriorate in patients receiving both furosemide and high doses of certain cephalosporins.

- Damage to hearing (ototoxicity) caused by aminoglycosides (e.g. kanamycin, gentamicin, tobramycin) and other ototoxic drugs may be increased by simultaneous administration of Lasix. Hearing impairment may not be reversible. Consequently, simultaneous use of the drugs mentioned above should be avoided.

- Simultaneous use of cisplatin (treatment for malignant diseases) and Lasix may result in hearing impairment. In addition, Lasix must be used with special care since it may enhance the harmful effect of cisplatin on the kidneys (nephrotoxicity).

- Simultaneous use of Lasix and lithium (used in certain forms of depression) 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 this combination.

- If other medicines used to reduce high blood pressure (antihypertensives) or diuretic drugs or products that may have a hypotensive effect are used at the same time as Lasix, a substantial decrease in blood pressure can be expected. Major drops in blood pressure, even leading to shock, and a deterioration of kidney function (with isolated cases of acute kidney failure) have been observed, particularly during initial administration of ACE inhibitors or angiotensin II receptor antagonists or during initial administration of higher doses. If possible, Lasix treatment should therefore be stopped temporarily, or at least the dose should be reduced for three days, before treatment with an ACE inhibitor or angiotensin II receptor antagonist is started or the dose increased.

- Lasix may reduce the elimination of probenecid, methotrexate, and other drugs which, like furosemide, are excreted via the kidneys. High-dose treatment may result in high levels of active substances in the blood and increase the risk of adverse effects.

- The effect of theophyllin (antiasmatic drug) or curare-like agents that cause muscle relaxation (muscle relaxants) may be enhanced by Lasix.

- The effect of drugs that lower blood sugar levels (antidiabetics) or increase blood pressure (pressor amines, e.g. adrenalin, noradrenalin) may be reduced by simultaneous use of Lasix.

- Caution is necessary in patients treated with risperidone, and the benefits and risks of using this combination or of simultaneous treatment with other potent diuretics should be carefully weighed by your doctor.

## Other interactions:

- Simultaneous use of cyclosporin A and Lasix 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 cyclosporin.

- In patients treated with furosemide who are at high risk for renal impairment during x-rays with contrast agents, renal function deteriorated more frequently after the examination in patients who received contrast materials than in those who only received intravenous fluids before the contrast-enhanced examination.

- In isolated cases, intravenous use of Lasix within 24 hours of administration of chloral hydrate resulted in sensations of warmth, sweating, agitation, nausea, and increased blood pressure and heart rate (tachycardia). Consequently, simultaneous use of Lasix and chloral hydrate should be avoided.

## Taking Lasix 40 mg tablets with food and drink

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

## Pregnancy and breast-feeding

Lasix 40 mg tablets must not be taken during pregnancy unless the attending physician considers it absolutely necessary, since the active substance furosemide crosses the placenta. Furosemide is excreted in breast milk and inhibits its production.

Consequently, you should not be treated with Lasix 40 mg tablets 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 extent that your ability to drive, use machines, or work without a safe footing is impaired. 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 Lasix 40 mg tablets

This medicine contains lactose. If you have known intolerance to some types of sugar, please consult your doctor first before taking this medicine.

## 3. HOW TO TAKE Lasix 40 mg tablets

Always take Lasix 40 mg tablets exactly according to your doctor's instructions. You should check with your doctor or pharmacist if you are unsure of anything.

## How many Lasix 40 mg tablets should be taken

Dosage should be determined on a case-by-case basis and above all depending on treatment response. 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) due to heart or liver disease:

The usual initial dose for adults is 1 x Lasix 40 mg tablet (equivalent to 40 mg of furosemide). If urine excretion is not sufficient, the single dose may be doubled after six hours to 2 x Lasix 40 mg tablets (equivalent to 80 mg of furosemide). If urine excretion is still insufficient, 4 x Lasix 40 mg tablets (equivalent to 160 mg of furosemide) may be taken after another six hours. If necessary, an initial dose of more than 200 mg of furosemide may be administered in exceptional cases under careful clinical monitoring.

The daily maintenance dose is generally 1 to 2 x Lasix 40 mg tablets (equivalent to 40 to 80 mg of furosemide).

Body weight loss caused by increased urine excretion should not exceed 1 kg/day.

### For fluid accumulation in tissue (edema) due to kidney disease:

The initial single dose for adults is usually 1 x Lasix 40 mg tablet (equivalent to 40 mg of furosemide) in the morning. If urine excretion is not sufficient, the single dose may be doubled after six hours to 2 x Lasix 40 mg tablets (equivalent to 80 mg of furosemide). If urine excretion is still insufficient, 4 x Lasix 40 mg tablets (equivalent to 160 mg of furosemide) may be taken after another six hours. If necessary, an initial dose of more than 200 mg of furosemide may be administered in exceptional cases under careful clinical monitoring.

The daily maintenance dose is generally 1 to 2 x Lasix 40 mg tablets (equivalent to 40 to 80 mg of furosemide).

Body weight loss caused by increased urine excretion should not exceed 1 kg/day.

In nephrotic syndrome, the dose must be carefully adjusted, due to the increased risk of adverse effects.

### For fluid accumulation in tissue (edema) due to burns:

The daily and/or single dose ranges from 1 to 2½ Lasix 40 mg tablets (equivalent to 40 to 100 mg of furosemide); in exceptional cases, in patients with kidney failure, the dose may be up to six Lasix 40 mg tablets (equivalent to 240 mg of furosemide).

Any decrease in fluid in blood vessels must be corrected before using Lasix 40 mg tablets.

### For high blood pressure (hypertension):

In general, take 1 x Lasix 40 mg tablet daily (equivalent to 40 mg of furosemide) alone or in combination with other drugs.

## Children:

Children should generally take 1 (or 2) mg of furosemide per kg body weight daily, and not more than 40 mg of furosemide daily.

#### How and how long Lasix 40 mg tablets should be taken for

Swallow the tablets whole on an empty stomach in the morning with enough liquid (e.g. with a glass of water).

The attending physician should decide on the duration of treatment. This is based on the type and severity of the disease.

#### If you take more Lasix 40 mg tablets than you should

If you suspect a significant overdose of Lasix 40 mg tablets, you should inform a doctor immediately. The doctor can decide on the measures that may be necessary, depending on the extent of overdose.

The signs of acute or chronic overdose depend on the severity of the salt and fluid loss.

Overdose may result in low blood pressure (hypotension) and circulatory disorders when changing from a lying to a standing position (orthostatic regulation disorders), electrolyte disturbances (decreased potassium, sodium, and chloride levels) and increased blood pH (alkalosis).

Severe fluid loss may result in dehydration and, due to blood volume losses (hypovolemia), in circulatory shock and thickening of the blood (hemoconcentration) with a tendency for thrombosis (blood clots).

Sudden water and electrolyte losses can result in a confusional state (delirious states).

#### If you forget to take Lasix 40 mg tablets

Do not take twice the amount next time, but continue taking the prescribed dose.

#### If you stop taking Lasix 40 mg tablets

You should not interrupt or prematurely stop treatment with Lasix 40 mg, tablets without consulting your doctor, as the success of your treatment may be at risk.

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

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Lasix 40 mg, tablets can cause side effects, although not everybody has them. In assessing the frequency of side effects, the following categories are used:

<b>Very common:</b>	more than 1 treated patient in 10
<b>Common:</b>	1 to 10 treated patients in 100
<b>Uncommon:</b>	1 to 10 treated patients in 1 000
<b>Rare:</b>	1 to 10 treated patients in 10 000
<b>Very rare:</b>	fewer than 1 treated patient in 10 000
<b>Unknown:</b>	cannot be estimated based on available data

#### Possible side effects

##### Blood

Uncommon: platelet depletion (thrombocytopenia).

Rare: Increase in certain white blood cells (eosinophilia), decrease in white blood cells (leukopenia).

Very rare: anemia due to increased decomposition 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).

##### Immune system/hypersensitivity reactions

Uncommon: itching, skin and mucosal reactions (see side effects on skin).

Rare: feverish state, inflammation of blood vessels (vasculitis), kidney inflammation (interstitial nephritis), serious hypersensitivity reactions such as circulatory shock (anaphylactic shock). The first signs of shock include skin reactions such as severe flushing or hives, agitation, headache, bout of sweating, nausea, and bluish discoloration of the skin (cyanosis).

##### Hormone system

The blood sugar level may increase under furosemide treatment. In patients with existing diabetes (manifest diabetes mellitus) this may lead to deterioration of the patient's metabolism. Underlying diabetes mellitus may become manifest.

##### Metabolism/electrolytes

Fluid and electrolyte disturbances are often observed during treatment with Lasix, due to increased elimination of fluids and electrolytes. For this reason, certain blood parameters should be tested regularly (especially potassium, sodium, and calcium).

Underlying diseases (e.g. liver cirrhosis, heart failure), simultaneous medication (see Section 2) and food are factors that may lead to electrolyte disturbances.

Due to increased sodium loss in the urine, a sodium deficit (hyponatremia) may occur, with corresponding symptoms, particularly if salt (sodium chloride) intake is reduced. Symptoms that are often reported with sodium deficit include apathy, calf cramps, loss of appetite, weakness, drowsiness, vomiting, and confusional state.

A potassium deficit may occur as a result of increased potassium excretion in the urine, especially if, during treatment, potassium intake is reduced or potassium loss increased (e.g. due to vomiting or chronic diarrhea). This condition may lead to symptoms such as muscle weakness, abnormal touch sensations in the hands and feet (paresthesia), minor paralysis (paresis), vomiting, constipation, build-up of gas in the digestive tract (tympanties), excessive urine output (polyuria), abnormal feeling of thirst with excessive fluid intake (polydipsia) and irregular pulse (e.g. excitation-conduction disorders). Severe potassium loss may result in bowel paralysis (paralytic ileus) or consciousness disorders and even coma.

Increased calcium excretion in the urine may cause a calcium deficit. In rare cases, this may result in neuromuscular hyperexcitability (tetany).

Increased magnesium loss in the urine may result in a magnesium deficit, and in rare cases, tetany and heart rate disorders have been reported.

Electrolyte and fluid loss during Lasix treatment may cause or exacerbate metabolic alkalosis (increased blood pH).

Blood uric acid levels are often increased during Lasix treatment. Predisposed patients are likely to suffer gout attacks.

Blood lipids (cholesterol, triglycerides) may increase during Lasix therapy.

##### Nervous system

Rare: A sensation of prickling or numbness in the hands and feet (paresthesia).

In patients with advanced liver failure, hepatic encephalopathy (a disease affecting the brain) may occur.

##### Sense organs

Due to the possible damage to hearing (ototoxicity) caused by Lasix, hearing disorders and/or noises in the ears (tinnitus) may occur in rare cases, which are usually curable (reversible). This can especially occur if the intravenous injection of Lasix is too rapid, particularly in patients who also have kidney failure or decreased blood protein levels (hypoproteinemia, e.g. in nephrotic syndrome).

##### Cardiovascular system

Excessive urine output may be accompanied by circulation disorders, especially in elderly patients and children, which are manifested in particular by headache, dizziness, sight disorders, dry mouth and thirst, low blood pressure (hypotension) and circulation disorders with a drop in blood pressure when changing from a lying to a standing position (orthostatic regulation disorders). Considerable (excessive) urine output may result in dehydration leading to decreased blood volume (hypovolemia), circulatory shock, and thickening of the blood (hemoconcentration). Hemoconcentration can increase patients' tendency for thrombosis (blood clots), particularly in the elderly.

##### Digestive tract

Rare: stomach and bowel disorders (e.g. nausea, vomiting, diarrhea).

##### Liver/pancreas

Very rare: acute inflammation of the pancreas, obstruction of bile flow (intrahepatic cholestasis), and increase in certain liver values (elevated transaminases).

##### Skin

Uncommon: itching, skin and mucosal reactions with redness, formation of blisters or scales (e.g.

bullous exanthema, hives, purpura, erythema multiforme, bullous pemphigoid, exfoliative dermatitis) and increased sensitivity to light (photosensitivity).

Rare: blood vessel inflammation (vasculitis).

##### Kidneys

Lasix treatment may cause a temporary increase in blood levels of substances that are eliminated by the kidneys (creatinine, urea).

Signs of impaired urine excretion (e.g. enlarged prostate, build-up of urine in the kidneys, narrowed ureter) may appear or worsen with Lasix. Urinary obstruction (urine retention) with complications may occur.

Rare: kidney inflammation (interstitial nephritis).

##### Newborns

In premature children treated with Lasix, kidney stones and/or calcification of kidney tissue may develop.

In premature infants with respiratory distress syndrome (major difficulty breathing) undergoing diuretic treatment with Lasix in the first weeks of life, there may be a higher risk that the vessel that shunts pulmonary circulation before birth will remain open (persistent patent ductus arteriosus).

##### General status

Rare: feverish state.

Should any of the side effects described above occur, inform your doctor as soon as possible, so that he/she can determine the severity and, if necessary, decide on further measures.

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 signs of a hypersensitivity reaction, Lasix 40 mg tablets should not be used again. If any of the above side effects worsen considerably, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5. HOW TO STORE Lasix 40 mg tablets

Keep out of the reach and sight of children.

Do not use after the expiry date given on the blister pack and box. The expiry date is the last day of the month stated.

##### Storage conditions:

Store in the original packaging to protect the contents from light.

Store below 25°C.

#### 6. FURTHER INFORMATION

##### What Lasix 40 mg tablets contain:

The active substance is furosemide.

One tablet contains 40 mg of furosemide.

The other ingredients are:

Lactose monohydrate, corn (maize) starch, pregelatinized corn (maize) starch, talc, colloidal silica, magnesium stearate (European Pharmacopoeia).

Note for diabetic patients: 1 tablet contains less than 0.01 bread units of carbohydrate.

##### What Lasix 40 mg tablets look like and contents of the pack:

Round, off-white tablets with a scoreline.

The tablets can be broken into two equal halves.

Boxes of 10, 20, 100 or 250 tablets in blisters (some presentations of the drug may not be marketed).

##### Dear patient,

Your doctor has prescribed this drug because you were found to have too much salt and/or water in your body.

Lasix 40 mg tablets act to eliminate this excess via the kidneys.

A healthy body contains 65% water, most of which is in cells, and the rest is in the fluid between the cells.

The "chemical" composition of our body and its fluids must remain within a very narrow range, so that single cells and hence the various organs can function normally. Large deviations from the normal range impair organ function and result in disease.

The kidneys are one of the most important organs ensuring chemical balance in the body. They remove metabolic waste products, excess minerals, foreign matter, and water from the blood.

One of these minerals is salt. Most people have two to three times too much salt in their daily diet.

Bear in mind that ready-meals, canned foods, and soup or sauce seasonings often contain too much salt. Tasty food can be prepared just as successfully if salt is replaced by herbs and spices such as basil, dill, tarragon, chervil, garlic, onions, paprika, and marjoram.

In some heart, liver, and kidney diseases, too much water accumulates in the tissues. The medical term for this accumulation of water is "edema." It first occurs mainly in the lower legs.

During medical washout of edema, the body loses potassium as well as salt. It is advisable to replace this potassium by eating potassium-rich food such as fresh vegetables and fruit, since potassium is important for the body and plays a role in metabolism. The recommended average daily requirement for adults is 2,500 mg of potassium.

Potassium content per 100 g of food (in mg)			
Vegetables		Fruit	
kohlrabi	230	grapes	254
asparagus	240	cherries	260
tomatoes	268	rhubarb	358
peas	380	bananas	420
cauliflower	400	Fresh fruit juices	
endives	400	orange juice	190
Brussels sprouts	400	apricot juice	440
potatoes	410		
spinach	489		

The table above shows some potassium-rich fresh vegetables, fruit, and fruit juices.

Occasionally, however, potassium salts may need to be administered, or medicines that help the body to retain potassium, in order to prevent potassium deficit.

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##### **This is a medication**

- A medication 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 medication
- 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
- Medicament: keep out of reach of children

Council of Arab Health Ministers  
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