PACKAGE LEAFLET: INFORMATION FOR THE USER

Furosemide 40 mg tablets

Active substance: furosemide

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT FUROSEMID 40 MG IS AND WHAT IT IS USED FOR

Furosemid 40 mg is a waterpill (diuretic).

Furosemid 40 mg is used in cases of
- accumulation of liquid in tissue (oedema) due to diseases of heart and liver
- accumulation of liquid in tissue (oedema) due to diseases of the kidneys (in case of nephrotic syndrome [loss of protein, disorder of the fat metabolism and accumulation of water] therapy of the basic disease has priority)
- accumulation of liquid in lung tissue (pulmonary oedema)
- high blood pressure (arterial hypertension)

2. BEFORE YOU TAKE FUROSEMID 40 MG

Do not take Furosemid 40 mg
- if you are hypersensitive (allergic) to furosemide, sulphonamides or to any of the other ingredients of Furosemid 40 mg
- in renal failure with lacking urinary production (anuria)
- in liver failure with clouding of consciousness (coma and hepatic precoma)
- in severe conditions of potassium deficiency
- in severe conditions of sodium deficiency
- in reduced volume of circulating blood (hypovolaemia) or lack of body fluid (dehydration)
- if you are breast-feeding (see also section “Take special care with Furosemid 40 mg”)

Take special care with Furosemid 40 mg
- if you have a considerably lowered blood pressure (hypotension)
- if you suffer from perfusion disorders of the blood vessels in the brain (cerebrovascular perfusion disorders) or of the coronary arteries (coronary heart disease), since you would be especially endangered in case of an undesirably high fall in blood pressure

- in already existing or not yet appeared diabetes mellitus (manifest or latent diabetes mellitus); regular monitoring of the blood sugar is necessary
- if you suffer from gout; regular monitoring of uric acid in the blood is necessary
- if you have an obstructed urinary outflow (e.g. in prostatic enlargement, hydronephrosis, ureterostenosis)
- in reduced content of protein in blood (hypoproteinaemia), e.g. in nephrotic syndrome [loss of protein, disorder of the fat metabolism and accumulation of water] (careful titration of the dosage is necessary in this case)
- if you suffer from severe liver disease (such as liver cirrhosis) and coincident impairment in renal function

In patients with **disorders of bladder emptying** (e.g. in patients with prostatic enlargement), Furosemid 40 mg may only be used if unrestricted urinary outflow is ensured, since sudden excessive passage of urine may lead to urinary retention with hyperextension of the bladder.

Concomitant use with risperidone
In risperidone placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients concomitantly treated with furosemide and risperidone when compared to patients treated with risperidone alone or furosemide alone. Caution should therefore be exercised and the risks and benefits of the combination or co-treatment with with other potent water pills should be weighed up by the doctor. The development of a deficit of body water (dehydration) should be avoided.

Children
Particularly careful monitoring is necessary in premature children, since there is the risk of the development of kidney calcifications or kidney stones.
Monitoring measures: monitoring of kidney function, ultrasonic examination of the kidneys.

In premature infants with conditions accompanied by dyspnoea (respiratory distress syndrome), diuretic treatment with Furosemid 40 mg during the first weeks of life can increase the risk that a vessel connection which avoids lung circulation before birth does not close (persistent Botallo'patients duct).

During long-term therapy with Furosemid 40 mg, certain blood values, particularly potassium, sodium, calcium, bicarbonate, creatinine, urea and uric acid as well as the blood sugar should be monitored at regular intervals. A particularly close monitoring is necessary if you are known to have a high risk of developing electrolyte disorders or in case of higher fluid losses (e.g. due to vomiting, diarrhoea or intense sweating). Reduced circulating volume of blood (hypovolaemia) or deficit of body water (dehydration) as well as considerable electrolyte disorders or disorders in the acid-base balance must be corrected. This may require treatment with Furosemid 40 mg to be discontinued temporarily.

The weight loss caused by increased urinary excretion should not exceed 1 kg/day, irrespective of the extent of urinary excretion.

In case of nephrotic syndrome (see above), the dosage established by the doctor must be followed particularly carefully due to the risk of side effects occurring with increased incidence.

Taking other medicines
Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

The effect of Furosemid 40 mg can be influenced during concomitant treatment with the following medicines or preparation groups:
- Glucocorticoids ("cortisone"), carbenoxolone or laxatives may lead to enhanced losses of potassium, with the risk of developing hypokalaemia
- Agents with anti-inflammatory effect (non-steroidal anti-inflammatory drugs, e.g. indometacin and acetylsalicylic acid) can attenuate the effect of Furosemid 40 mg. If the volume of circulating blood

decreases (hypovolaemia) during treatment with Furosemid 40 mg or in case of deficit of body water (dehydration), concurrent administration of non-steroidal anti-inflammatory drugs can induce acute renal failure.
- Probenecid (agent against gout), methotrexate (agent against rheumatism and agent to suppress immune defence) and other medicines - like furosemide secreted in the kidney - can attenuate the effect of Furosemid 40 mg.
- In concomitant administration of phenytoin (agent against seizures and certain forms of pain), an attenuated effect of Furosemid 40 mg was described.
- Since sucralfate (gastric agent) reduces the uptake of Furosemid 40 mg from the intestine and thus attenuates its effect, both medicines should be taken at an interval of at least 2 hours.

The effect of the following medicines or preparation groups can be influenced during concomitant treatment with Furosemid 40 mg:
- It is to be heeded in concomitant treatment with certain heart agents (glycosides) that in a state of potassium deficiency or magnesium deficiency developing during therapy with Furosemid 40 mg, the sensitivity of the heart muscle towards these heart agents is increased. There is an aggravated risk of cardiac dysrhythmias (ventricular arrhythmias including *torsades de pointes*) in concomitant use of medicines which may cause a certain ECG change (syndrome of prolonged QT interval) (e.g. terfenadine – agent against allergies –, some agents against cardiac dysrhythmias [antiarrhythmics of classes I and III]) and in the presence of electrolyte disorders.
- The side effects of high-dosed salicylates (painkillers) can be enhanced during concomitant use of Furosemid 40 mg.
- Furosemid 40 mg can enhance the toxic effects of kidney-damaging (nephrotoxic) medicines (e.g. antibiotics such as aminoglycoside, cephalosporins, polymyxins).
- In patients concomitantly treated with furosemide and high doses of certain cephalosporins, kidney function can exacerbate.
- The hearing-damaging effect (ototoxicity) of aminoglycosides (e.g. kanamycin, gentamicin, tobramycin) and other ototoxic medicines may be increased in concomitant administration of Furosemid 40 mg. Hearing disorders can be irreversible. Concomitant use of the above-named medicines should therefore be avoided.
- If Furosemid 40 mg is used concomitantly with cisplatin (agent against malignant diseases), the possibility of auditory damage is to be expected. Furosemid 40 mg must be given with special caution, since an enhancement of the kidney-damaging effect (nephrotoxicity) of cisplatin can occur.
- Co-administration of Furosemid 40 mg and lithium (agent against certain forms of depression) can lead to an increase in the heart- and nerve-damaging (cardiotoxic and neurotoxic) effects of lithium. It is therefore recommended to carefully monitor the lithium blood level of patients receiving this combination.
- If other blood pressure-lowering medicines, waterpills (diuretics) or medicines with blood pressure-lowering potential are used concomitantly with Furosemid 40 mg, a higher fall in blood pressure is to be expected. Massive falls in blood pressure up to shock and exacerbation of renal function (in isolated cases acute renal failure) have particularly been observed if an ACE inhibitor or angiotensin-II-receptor antagonist was administered for the first time or at higher dosage for the first time. If possible, Furosemid 40 mg therapy should therefore transiently be discontinued or at least the dose be reduced for three days before therapy with an ACE inhibitor or angiotensin-II-receptor antagonist is initiated or its dose increased.
- Furosemid 40 mg can reduce the excretion of probenecid, methotrexate and other medicines secreted in the kidney like furosemide. In case of high-dosed treatment, this can lead to elevated agent levels and a higher risk of side effects.
- The effect of theophylline (agent against asthma) or curariform agents that induce muscle relaxation (muscle relaxants) can be potentiated due to Furosemid 40 mg.

Attenuated effect of other medicines:
The effect of blood sugar-lowering medicines (antidiabetics) or blood pressure-raising agents (pressor amines, e.g. epinephrine, norepinephrine) can be attenuated in concomitant use of Furosemid 40 mg.

Caution is required in patients treated with **risperidone**. Risks and benefits of the combination or co-treatment with furosemide or with other potent water pills should be weighed up by the doctor.

Using Furosemid 40 mg with food and drink
Liquorice in combination with Furosemid 40 mg can lead to enhanced potassium losses.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You may use Furosemid 40 mg during pregnancy only if the attending doctor deems this compellingly necessary, because the active substance furosemide passes the placenta.

Breast-feeding
Furosemide is excreted into mother'patients milk and inhibits the production of mother's milk. You must therefore not be treated with Furosemid 40 mg if you are breast-feeding.
If necessary, you must stop breast-feeding (see also section "Do not take Furosemid 40 mg").

Driving and using machines
Even if used as directed, this medicine can alter reactivity to such an extent that the ability to drive, use machines or to work in potentially hazardous situations is impaired. This applies to a higher extent at the onset of treatment, when increasing the dose or changing preparations as well as in conjunction with alcohol.

Effects in association with misuse for doping purposes
Use of Furosemid 40 mg can lead to positive results in doping tests.

Abusive use of the medicine Furosemid 40 mg for doping purposes can jeopardize your health.

Important information about some of the ingredients of Furosemid 40 mg
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Furosemid 40 mg.

3. HOW TO TAKE FUROSEMID 40 MG

Always take Furosemid 40 mg exactly as your doctor has told you. You should check with your doctor if you are not sure.

The dosage should be established on an individual basis, especially according to the therapeutic success and should not be changed without the doctor'patients instruction. The lowest dose is always to be used with which the desired effect will be achieved.

If not otherwise prescribed by the doctor, the usual dose is:
Adults
Accumulation of liquid in tissue (oedema) due to diseases of heart or liver

As a rule, adults take an initial dose of ½−1 tablet of Furosemid 40 mg (equivalent to 20−40 mg furosemide). If a satisfactory urinary excretion fails to appear, the single dose may be doubled to 2 tablets of Furosemid 40 mg (equivalent to 80 mg furosemide) after 6 hours. If an adequate urinary excretion continues to be missing, a further 4 tablets of Furosemid 40 mg (equivalent to 160 mg furosemide) may be administered after another 6 hours.

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

Accumulation of liquid in tissue (oedema) due to diseases of the kidneys

As a rule, adults take as initial dose 1 tablet of Furosemid 40 mg (equivalent to 40 mg furosemide). If a satisfactory diuresis fails to appear, the single dose may be doubled to 2 tablets of Furosemid 40 mg (equivalent to 80 mg furosemide) after 6 hours. If an adequate urinary excretion continues to be missing, a further 4 tablets of Furosemid 40 mg (equivalent to 160 mg furosemide) may be administered after another 6 hours.

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

In case of a nephrotic syndrome, the dose must be chosen with caution due to the risk of a higher incidence of side effects.

High blood pressure (arterial hypertension)
As a rule, 1 tablet of Furosemid 40 mg (equivalent to 40 mg furosemide) once daily. If necessary your doctor may increase the dose up to 1½ tablets of Furosemid 40 mg (equivalent to 60 mg furosmide) once daily.

Children
In general, children receive 2 mg furosemide per kg bodyweight and day, 40 mg furosemide per day at a maximum.

Method of use
Take the tablets on an empty stomach and without chewing with sufficient liquid (e.g. a glass of water).

Noteforuse
To divide the tablet, it is put on a solid ground with the score upwards. The tablet is divided by pressing the fingers on the right and left of the score.

Duration of use
The attending doctor decides on the duration of use. It depends on the type and severity of the disease.

Please speak with your doctor or pharmacist if you have the impression that the effect of Furosemid 40 mg is too strong or too weak.

If you take more Furosemid 40 mg than you should
If an overdose with larger quantities of Furosemid 40 mg is suspected, a doctor is to be informed immediately. He can decide on possible, if at all necessary measures, according to the severity of the overdose.

The signs of an acute or chronic overdose depend on the extent of the salt and fluid losses.

Overdose may lead to lowered blood pressure (hypotension) and circulatory disorders when changing from lying to standing (orthostatic dysregulation), electrolyte disturbances (lowered potassium, sodium and chloride levels) or increased pH value in the blood (alkalosis).

Major loss of fluid can result in marked “dewatering” (dehydration) and, as a result of reduced volume of circulating blood (hypovolaemia), to circulatory collapse and thickening of blood (haemoconcentration) with tendency to thrombosis.

States of confusion (delirious disorders) may occur in connection with rapid losses of water and electrolytes.

If you forget to take Furosemid 40 mg
Do not take a double dose if you have forgotten the preceding intake, but continue intake at the prescribed dosage.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Furosemid 40 mg can cause side effects, although not everybody gets them.

The evaluation of undesirable effects is based on the following categories:

Very common	(> 1/10)
Common	(> 1/100, < 1/10)
Uncommon	(> 1/1,000, < 1/100)
Rare	(> 1/10,000, < 1/1,000)
Very rare	(< 1/10,000)
Not known	(cannot be estimated from the available data)

Blood and lymphatic system disorders
Uncommon:
- Reduction in blood platelets (thrombocytopenia)

Rare:
- Increase in certain white blood cells (eosinophilia)
- Reduction in white blood cells (leukopenia)

Very rare:
- Anaemia due to increased breakdown of red blood cells (haemolytic anaemia)
- Anaemia due to impaired blood formation in the bone marrow (aplastic anaemia)
- High-grade reduction in certain white blood cells with tendency to infections and severe general symptoms (agranulocytosis)

Immune system disorders
Uncommon:
- Itching
- Skin and mucosal reactions (see side effects of the skin)

Rare:
- Febrile conditions, inflammation of vessels (vasculitis), inflammation of the kidneys (interstitial nephritis), severe hypersensitivity reactions such as circulatory collapse (anaphylactic shock). First signs of a shock are – among others – skin reactions such as severe skin reddening (flush) or nettle rash, restlessness, headache, fit of perspiration, nausea and bluish discoloration of the skin (cyanosis)

At first signs of a hypersensitivity reaction, Furosemid 40 mg must not be taken again.

Endocrine disorders
The blood sugar level can rise during treatment with furosemide. This can lead to an exacerbation of the metabolic state in patients with already existing diabetes (manifest diabetes mellitus). Diabetes not yet appeared (latent diabetes mellitus) can become manifest.

Metabolism and nutrition disorders
Disorders in electrolyte and fluid balances as a consequence of increased fluid and electrolyte excretion are *commonly* observed during therapy with Furosemid 40 mg. Regular monitoring of certain blood values (especially potassium, sodium and calcium) is therefore indicated.

As a result of elevated sodium losses via the kidney, sodium deficiency states with corresponding symptomatology may occur, especially in restricted supply of salt (sodium chloride). Commonly observed

symptoms of a sodium deficiency condition are apathy, cramp in the calf, loss of appetite, weakness, sleepiness, vomiting and states of confusion.
Especially in concomitantly reduced potassium supply or increased potassium losses (e.g. in vomiting or chronic diarrhoea), increased potassium excretion via the kidney may result in potassium deficiency, which manifests itself in symptoms such as muscle weakness, sensory disorders in extremities (paraesthesia), paralyses (pareses), vomiting, constipation, excessive accumulation of gas in the gastrointestinal tract (meteorism), excessive urinary excretion (polyuria), pathologically increased sensation of thirst with excessive fluid uptake (polydipsia) and irregular pulse (e.g. impaired stimulant formation and conduction of the heart). Severe potassium losses may lead to intestinal paralysis (paralytic ileus) or depression of consciousness up to coma.

Increased calcium excretion via the kidney can lead to calcium deficiency. This can induce a condition of neuromuscular overexcitability (tetania) in rare cases.

Elevated magnesium losses via the kidney can result in magnesium deficiency; tetania or the occurrence of arrhythmia was observed in rare cases.

Metabolic alkalosis (increase in the pH value in the blood) may develop or already existing metabolic alkalosis may deteriorate as a result of electrolyte and fluid losses during treatment with Furosemid 40 mg.

Increased uric acid levels in the blood *commonly* occur during therapy with Furosemid 40 mg. This may lead to gout attacks in predisposed patients.

Increase in blood fats (cholesterol, triglycerides) in the blood can occur on Furosemid 40 mg.

Nervous system disorders
Rare:
- Tingling or sensation of numbness in extremities (paraesthesia)

Hepatic encephalopathy can occur in patients with hepatic insufficiency.

Ear and labyrinth disorders
Rare:
Owing to the hearing-damaging effect (ototoxicity) of Furosemid 40 mg, mostly reversible hearing disorders or noises in the ear (tinnitus) occur.

Cardiac disorders
In excessive urinary excretion, circulatory complaints may occur, especially in elderly patients and in children, which predominantly manifest themselves as headache, dizziness, visual disturbances, dry mouth and thirst, lowered blood pressure (hypotension) and circulatory disorders when changing from lying to standing (orthostatic dysregulation). “Dewatering” (dehydration) and - as a consequence of reduced volume of circulating blood (hypovolaemia) - circulatory collapse and blood thickening (haemoconcentration) may occur in very strong (excessive) urinary excretion.

As a result of haemoconcentration, increased tendency to thromboses may occur, particularly in elderly patients.

Vascular disorders
Rare:
- Inflammation of blood vessels (vasculitis)

Gastrointestinal disorders
Rare:
- Gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea)

Hepatobiliary disorders

Very rare:
- Acute pancreatitis
- Biliary congestion (intrahepatic cholestasis)
- Increase in certain liver values (transaminase increase)

Skin and subcutaneous tissue disorders
Uncommon:
- Itching
- Skin and mucosal reactions with reddening, blistering or scaling, e.g. bullous exanthema, urticaria, purpura, erythema multiforme, bullous pemphigoid, exfoliative dermatitis, and increased sensitivity to light (photosensitivity).

Renal and urinary disorders
Rare:
- Inflammation of the kidney (interstitial nephritis)

Pregnancy, puerperium and perinatal conditions
Immature children treated with Furosemid 40 mg may develop kidney stones and/or chalky deposits in kidney tissue.

In immature children with respiratory distress syndrome, diuretic treatment with Furosemid 40 mg can increase the risk that a vessel connection which avoids lung circulation before birth does not close (persistent Botallo'patients duct).

If you observe the above-named side effects, inform your doctor as soon as possible, so that he/she can decide on the severity and possible, if at all necessary further measures.

If a side effect suddenly occurs or develops intensely, immediately inform a doctor, as certain drug side effects may possibly become life-threatening. The doctor decides which measures are to be taken and whether therapy may be continued.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FUROSEMID 40 MG

Keep out of the reach and sight of children.

Do not use the medicine after the expiry date which is stated on the blister and outer carton after "EXP". The expiry date refers to the last day of that month.

Storage conditions
Blister:
Keep the blister in the outer carton in order to protect from light.

Tablet container:
This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Furosemid 40 mg contains

The active substance is: **furosemide**.
1 tablet contains 40 mg furosemide.
The other ingredients are:
microcrystalline cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium starch glycollate

What Furosemid 40 mg looks like and contents of the pack
White, round, slightly convex tablet with one-sided score

The tablet can be divided into equal halves.

Furosemid 40 mg is available in Polypropylen/Aluminium blisters containing 10, 12, 14, 20, 28, 30, 50, 56, 60, 84, 100 and 250 tablets

or in HDPE-bottles containing 100 and 250 tablets.

Not all packs sizes or pack types may be marketed.

Marketing Authorisation Holder
SANDOZ GmbH,KUNDL BIOCHEMIESTRASSE 106250 AUSTRIA.

Manufacturer
Sandoz Private Limited
Plot No. 8-A/2 & 8-B
TTC Industrial Area
Kalwe Block, Village-Dighe
Navi Mumbai 400 708
India
Final release Releaser
Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Germany
This leaflet was last revised in January 2016