

Package leaflet: information for the user

Furosemide Auro 40 mg, tablets
furosemide

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Furosemide Auro and what is it used for?

Furosemide belongs to the group of so-called loop diuretics (a certain type of diuretics). It promotes the excretion of water and salts through the urine. This helps to lower high blood pressure, among other things. The effect starts about half an hour after ingestion and lasts about 4-6 hours.

This medicine is used for:

fluid retention (edema) caused by heart, liver, or kidney disorders
fluid accumulation in the lungs (pulmonary edema)
increased blood pressure (hypertension), where the blood pressure is slightly or moderately elevated; in cases of severe high blood pressure, a combined treatment with other antihypertensive medications is recommended
sudden excess of calcium in the blood (acute hypercalcemia).

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

You are allergic to certain medications that inhibit bacterial growth (sulfonamides; e.g., sulfonamide antibiotics or sulfonyleureas). You may also be allergic to furosemide

You have insufficient blood volume (hypovolemia) or suffer from dehydration

Your urine output is absent (anuria) due to insufficient kidney function (renal insufficiency)

You have too little potassium in your blood, in severe form recognizable by muscle cramps or muscle weakness and fatigue (hypokalemia)

You have too little sodium in your blood (hyponatremia)

You have a severe liver condition (precomatose and comatose hepatic encephalopathy)

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine:

if you have low blood pressure (hypotension); your doctor will monitor you regularly if you are older, if you are taking other medication that can lead to a drop in blood pressure, and if you have other medical conditions that put you at risk of a drop in blood pressure.

if you suffer from a significant drop in blood pressure, e.g., due to narrowing of the coronary arteries or the blood vessels supplying the brain; your doctor will monitor you regularly

if you have latent (dormant) or manifesting (clearly visible) diabetes mellitus; your doctor will monitor you regularly

if you have inflammation of the joints caused by the deposition of uric acid crystals (gout); your doctor will monitor you regularly

if your kidneys are not functioning well and you have a severe liver disease (hepatorenal syndrome); your doctor will regularly monitor you

if you have a low protein level in your blood (hypoproteinemia); your doctor will regularly monitor you

in premature infants; the doctor will regularly monitor your baby

if you suffer from liver disease (cirrhosis) and are simultaneously treated with adrenal cortex hormones (corticosteroids), consume a one-sided diet, or abuse laxatives; a potassium deficiency in the blood may occur (hypokalemia). Your doctor will regularly check your blood. With prolonged use of furosemide, the doctor may prescribe a potassium-rich diet (potatoes, bananas, tomatoes, citrus fruits, fruit juices, dried fruits, cauliflower, and spinach)

if you use high doses of furosemide, it is recommended to monitor the thyroid hormone level

if you suffer from an existing carbohydrate intolerance or diabetes mellitus; these conditions may worsen; your doctor will regularly monitor your blood glucose level

if you have impaired kidney function resulting in frequent urination; you should ensure adequate fluid intake (by drinking)

if you have a partial blockage of the urinary tract, for example, due to hydronephrosis, kidney stones (nephrolithiasis), bladder disorders, prostate enlargement (prostatic hyperplasia), narrowing of the ureter (ureteral stricture), this can cause or worsen increased urine production and complaints; your doctor will regularly monitor you, especially during the initial phase of treatment

if you suffer from an existing increase in blood acidity (pH) due to acid loss (metabolic alkalosis); this can be worsened by furosemide. With prolonged use, the doctor will regularly monitor you

if you suffer from too much calcium in the blood (acute hypercalcemia) as a result of vomiting and urine excretion (diuresis); your doctor will monitor you more frequently

if you suffer from dementia and are treated with risperidone (see also “Are you taking any other medicines”).

Consult your doctor if any of the above warnings apply to you or have applied in the past.

Are you taking any other medicines?

Are you taking any other medicines besides Furosemide Auro, have you recently taken any, or are you planning to take any soon? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription.

Tell your doctor especially if you are taking the following medicines:

Aliskiren – used to treat high blood pressure
adrenal cortex hormones with, among others, an anti-inflammatory effect (corticosteroids), carbenoxolone, increased alcohol consumption, and abuse of laxatives; this can lead to too little potassium in the blood (hypokalemia)
heart medications (e.g., digoxin); the toxicity of these medications can be increased by a disturbed electrolyte balance (e.g., too little potassium and sodium in the blood)
medications that treat diabetes (antidiabetics); the effectiveness of these medications can be reduced
blood pressure-raising medications (so-called sympathomimetics, such as epinephrine and norepinephrine); the effectiveness of these medications can be reduced
muscle relaxant medications (muscle relaxants) and theophylline (medication for asthma); the effects of these medications may be enhanced
certain antibiotics (medications for the prevention/treatment of certain infections); the kidneys and hearing can be damaged by these medications. The hearing disorders may be permanent
cephalosporins; kidney damage may occur, especially when your kidneys are not functioning well
cyclosporin A; there is an increased risk of developing joint inflammations (gout-like arthritis)
medications excreted via the kidneys, such as probenecid (medication for pain) and methotrexate (medication that suppresses the natural immune response (immunosuppressants)); these medications reduce the effect of furosemide
lithium preparations (medications for depression); the risk of lithium poisoning is increased (lithium intoxication); your doctor will regularly check the lithium concentration in your blood
oral blood sugar-lowering medications and medications that increase blood pressure (pressor amines); furosemide weakens the effect of these medications
blood pressure-lowering medications (antihypertensives) and ACE inhibitors (a certain group of blood pressure-lowering medications); furosemide enhances the effect of these medications
certain group of pain-relieving medications with anti-inflammatory and fever-reducing effects (NSAIDs, such as indomethacin and acetylsalicylic acid); the blood pressure-lowering effect of furosemide is counteracted
phenytoin (medication for epilepsy); the urine-promoting (diuretic) effect of furosemide decreases

cisplatin (medication for cancer); concurrent use with furosemide can lead to hearing damage
sucralfate (medication that protects the stomach lining (mucosal protectants)); the absorption of furosemide via the intestines is counteracted, reducing the effect of furosemide; furosemide and sucralfate should not be taken within 2 hours of each other
risperidone (medication for psychosis); concurrent use with furosemide may increase the risk of stroke or death in elderly people with dementia.

Your doctor may need to change your dose and/or take other precautions if you are using any of the following medications:

Aliskiren - used to treat high blood pressure.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Pregnancy

During pregnancy, furosemide should only be used on the advice of a doctor and solely for fluid retention (edema) that is not directly or indirectly related to the pregnancy.

A limited amount of data on the use of furosemide during pregnancy in humans does not indicate an increased risk of congenital abnormalities, but adverse effects have been demonstrated in animal studies.

Furosemide crosses the placenta, which may cause the fetus to have increased urine excretion (diuresis). Your doctor will closely monitor your blood levels and the growth of the fetus.

Breastfeeding

Furosemide may potentially reduce the amount of breast milk. Furosemide is present in breast milk. The effect of furosemide on newborns/infants is not known.

Your doctor will decide in consultation with you whether it is better to stop treatment with furosemide or to stop breastfeeding.

Fertility

There are no known data on the possible influence of furosemide on fertility in humans.

Ask your doctor or pharmacist for advice before taking any medication.

Driving and using machines

The ability to participate in traffic or operate machines may be adversely affected in rare cases by the use of furosemide. This occurs especially at the start of treatment, when changing medication, and in combination with alcohol.

Furosemide Auro contains lactose

If your doctor has informed you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The doctor decides how to proceed in each individual case. The duration and degree of fluid excretion depend on the patient's condition. It usually begins within an hour and can last 4-8 hours. Generally, excretion is strongest at the start of treatment.

The usual dosage is:

Adults:

Edema caused by heart conditions

The starting dose is 20 to 80 mg per day, divided into 2 to 3 doses.

The daily maintenance dose is 40 mg every other day.

The maximum daily dosage is 1500 mg.

Edema caused by liver or kidney disorders

The starting dosage is 40 to 80 mg per day, given as a single dose or divided into 2 to 3 doses.

The daily maintenance dosage is 40 mg every other day.

The maximum daily dosage is 1500 mg.

Hypertension

Furosemide can be used alone for this or in combination with other antihypertensive medications (medications that lower blood pressure).

The daily maintenance dosage is 20 to 40 mg per day.

The maximum daily dosage is 1500 mg.

Pulmonary edema and acute hypercalcemia

The starting and maintenance dosage is 40 mg every other day. In severe cases, it may be necessary to start with 40 mg per day or 80-120 mg per day. The maximum daily dosage is 1500 mg.

Use in children:

Special guidelines apply for dosing in children (guideline: 1-3 mg per kg body weight with a maximum of 40 mg per day).

Take the tablets or tablet parts with water on an empty stomach. Do not chew the tablets.

If you notice that Furosemide Auro is too strong or not strong enough, consult your doctor or pharmacist.

Have you taken too much of this medicine?

If you have taken too much of Furosemide Auro, you must immediately contact a doctor.

Symptoms of overdose may include: sudden lowered blood pressure (acute hypotension), dehydration, and deficiency of certain substances in the body (electrolyte deficiency).

Have you forgotten to take this medicine?

If you have forgotten to take a dose, you should do so as soon as possible.

If the time until the next dose is shorter than the time until the missed dose, you do not need to do anything. It is better to skip one dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Never change the dosage yourself and never stop the treatment yourself, even if you experience side effects. Consult your doctor first. He/she can tell you if you can stop and how best to do so.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects. Not everyone experiences them.

The side effects that may occur with furosemide are usually related to the water and salt excreting effect of furosemide.

Side effects that may occur are:

Very common (occur in more than 1 in 10 users)

Disturbances in the mineral balance (electrolyte disturbances), dehydration, and insufficient blood volume, especially in older patients.

Common (occur in less than 1 in 10 users)

Thickening of the blood.

Lowered minerals (sodium, chloride, and/or potassium) in your blood, gout attacks.

Brain disorder characterized by, for example, seizures and reduced consciousness due to insufficient liver function (hepatic encephalopathy).

Sometimes (occur in less than 1 in 100 users)

Blood disorder (lack of platelets) accompanied by bruising and bleeding tendency (thrombocytopenia).

Hearing disorders. Deafness (sometimes irreversible).

Nausea.

Hypersensitivity reactions such as itching, skin rash with severe itching and formation of welts (hives or urticaria), skin rash (rash), severe hypersensitivity reaction with (high) fever, skin rash with red (moist) irregular spots (erythema multiforme), blistering in the skin or mucous membranes (pemphigoid), skin rash with Peeling of the upper skin layers, red spots on the skin, pinpoint bleeding in the skin (purpura), sensitivity to light (photosensitivity).

Rare (occur in less than 1 in 1000 users)

Blood disorder (lack of white blood cells) accompanied by increased susceptibility to infections (leukopenia), increase of certain substances (eosinophilic cells) in the blood (eosinophilia).

Severe reactions (sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, reduced consciousness) due to a sudden strong vasodilation as a result of severe hypersensitivity to certain substances (anaphylactic reaction).

Perception of tingling, itching, or tingling without any reason (paresthesias), life-threatening form of unconsciousness (hyperosmolar coma).

ringing in the ears (tinnitus).

Inflammation of a blood vessel (vasculitis).

Gastrointestinal complaints, such as vomiting or diarrhea.

Joint pain and/or eye inflammation (Stevens-Johnson syndrome), severe, acute (hypersensitivity) reaction accompanied by fever and blisters on the skin/peeling of the skin (toxic epidermal necrolysis).

Inflammation of the kidneys accompanied by blood in the urine, fever, and pain in the flanks (interstitial nephritis).

Fever.

Very rare (occur in less than 1 in 10,000 users)

Anemia due to lack of red blood cells (aplastic anemia) and anemia due to excessive breakdown of blood (hemolytic anemia), very severe blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis).

Certain liver function disorders (cholestasis), increase of certain enzymes (transaminases), sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen radiating to the back and nausea and vomiting (acute pancreatitis).

Unknown (cannot be determined with the available data)

It may occur that you can no longer tolerate certain sugars (glucose) due to the use of furosemide. If you have diabetes mellitus, you may no longer be able to accurately measure certain values in your blood.

Reduced calcium and/or magnesium in your blood, increase in blood acidity (pH) due to acid loss (metabolic alkalosis), Pseudo-Bartter syndrome which can result in fluid retention in body tissue.

Dizziness, fainting, and loss of consciousness (caused by symptomatic hypotension), headache.

Lowered blood pressure.

Thrombosis.

Sudden blisters with pus on the body, autoimmune disease characterized by blistering of the skin or mucous membranes.

Acute generalized exanthematous pustulosis (AGEP) (acute skin rash).

Lichenoid reactions characterized as small, itchy, reddish-purple, polygonal lesions on the skin, genitals, or in the mouth.

Sudden retention of urine in the bladder due to impaired bladder emptying (urinary retention) in patients with partial obstruction of the urinary tract, kidney failure.

Increased risk of non-closure of the ductus arteriosus (aorta in the fetus) after birth in premature infants with certain respiratory disorders (respiratory distress syndrome).

1) Furosemide can lead to excessive loss of body fluids (e.g., more frequent urination than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that may occur include: thirst, headache, confusion, muscle cramps, increased muscle irritability (tetany), muscle weakness, cardiac arrhythmias, and gastrointestinal disorders. Furosemide can also lead to an increase in blood acidity (pH) due to acid loss (metabolic alkalosis); this usually occurs at high doses and is influenced by an underlying disorder (e.g., severe liver disease (cirrhosis) characterized by permanent damage to liver tissue or heart failure (insufficient pumping power of the heart)), when other medication is given simultaneously, and by diet.

In case of sodium deficiency (hyponatremia):

- calf cramps
- lack of appetite
- lethargy (apathy)
- feeling of weakness
- dizziness
- drowsiness
- vomiting
- confusion.

In case of potassium deficiency (hypokalemia):

- muscle weakness and the inability to contract one or more muscles (paralysis)
- gastrointestinal symptoms, such as vomiting, constipation, and flatulence (meteorism)
- increased urine output (polyuria)
- cardiac symptoms
- in case of severe potassium loss: obstruction of bowel function (paralytic ileus) or confusion, which can result in coma.

In case of magnesium and calcium deficiency:

- increased irritability of the muscles (tetany)
- arrhythmias.

2) Lowering of blood pressure, resulting in reduced concentration and reactions, lightheadedness, feeling of pressure on the head, headache, dizziness, drowsiness, feeling of weakness, disturbed vision, dry mouth, and inability to stand upright (orthostatic intolerance). In the elderly, this can lead to too low blood volume (hypovolemia), dehydration, and thickening of the blood (hemoconcentration); this can cause blood clots to form in the blood vessels (thrombosis).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Store in the original package to protect from light. Store below 25°C.

Do not use this medicine after the expiry date. You will find this on the packaging and on the blister strips after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is furosemide.

The other substances in this medicine are lactose monohydrate, maize starch, povidone K-25, magnesium stearate (E470b), and talc (E553b).

What does Furosemide Auro look like and what is in a package?

The tablets are white and round with a diameter of approximately 8 mm and have a score line.

The tablet can be divided into equal halves.

The tablets are available in blister packs of 30 or 500 pieces and in bottle packaging of 500 pieces.

Marketing authorization holder and manufacturer

Marketing authorization holder Aurobindo Pharma B.V.

Baarnsche Dijk 1
3741 LN Baarn
Netherlands

Manufacturer:
Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn
Netherlands

The medicine is registered under:

RVG 53385 Furosemide Auro 40 mg, tabletn

This leaflet was last approved in March 2024.