Package leaflet: Information for the patient

Furosemid Slavia 40 mg tablets
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 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 of the 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 Furosemid Slavia is and what it is used for

Furosemid Slavia contains furosemide, a substance belonging to a group of medications called loop diuretics with intense action.

Furosemid Slavia is indicated in the treatment of oedema associated with heart failure, hepatic cirrhosis or renal conditions. It can be used in severe oedema and in those resistant to thiazide diuretics, possibly in combination with them. It can also be associated with potassium-sparing diuretic.

Furosemide remains effective even in conditions of reduced glomerular filtration, such as in cases of severe renal failure.

It is indicated for mild to moderate hypertension, either alone or in combination with other antihypertensive drugs.

Furthermore, it is indicated in certain cases of acute renal failure with oliguria (a decrease in the amount of urine produced in a 24-hour period): it may alleviate oliguria, but likely does not influence the progression of renal failure.

2. What you need to know before you take Furosemid Slavia

Do not take Furosemid Slavia if you:
- are allergic to furosemide, other sulphonamide related medicines or any of the other ingredients of this medicine (listed in section 6);
- have a urinary tract obstruction with oliguria (decreased amount of urine excreted over 24 hours);
- suffer from kidney failure with anuria (pathological cessation of urination);

- are dehydrated;
- have low blood pressure;
- take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. amiloride or spironolactone);
- suffer from hepatic encephalopathy (acute or chronic cerebral dysfunction, potentially reversible and repetitive, resulting from lesions in the central nervous system or neuromuscular system) or hepatic cirrhosis;
- have digitalis poisoning;
- are breast-feeding;
- in children under 6 years of age.

Warnings and precautions
Before taking Furosemid Slavia, consult your doctor or your pharmacist. Tell your doctor or pharmacist before taking this medication if you:
- have hypovolemia (reduced circulating blood volume) or are at risk of developing arterial hypotension;
- have hypoproteinemia (reduced protein levels in the blood) as a result of renal impairment;
- have hepatic congestion (slowing of blood flow through vessels) or other liver problems;
- have kidney problems;
- have diabetes mellitus or latent diabetes mellitus;
- you are an elderly patient;
- have prostate problems or experience difficulty urinating;
- have gout;
- have acute porphyria (a disease caused by some disorders in the metabolism of blood pigment).

If you are elderly, if you are on other medications which can cause the drop the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure, talk to your doctor or pharmacist.

Children
In premature infants, it may lead to the development of calcium crystals in the kidneys and the formation of kidney stones (nephrocalcinosis/nephrolithiasis).

Athletes
Athletes should be cautioned that furosemide may result in a positive doping test result during anti-doping control.

Other medicines and Furosemid Slavia
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. If you are taking any of the medicines listed below, you should take care:
- medications used to treat high blood pressure such as *angiotensin converting enzyme (ACE), alpha-blockers (prazosin, doxazosin), calcium channel blockers, diuretics;*
- medications for treating mental illnesses, such as *amisulpride*;
- medications for arrhythmia, such as *amiodarone, sotalol*;
- digoxin;
- nitrates for angina pectoris;
- lithium for depression or mania;
- cholesterol-lowering medications, such as *cholestyramine*;
- nonsteroidal anti-inflammatory drugs (*NSAIDs*), such as *indomethacin, acetylsalicylic acid*;
- antibiotics that have toxic effects on hearing and kidneys, such *as gentamicin, vancomycin, cefaclor, colistin*;
- medications for treating fungal infections, such as *amphotericin*;
- medications for treating depression (*monoamine oxidase inhibitors* - MAOIs);
- medications for treating diabetes, such as *insulin, metformin*, etc.;

- medications for treating epilepsy, such as *phenytoin, carbamazepine*;
- medications for treating allergic reactions (corticosteroids or antihistamines);
- medications for treating ADHD;
- medications for treating cancer;
- levodopa for Parkinson's disease;
- oral contraceptives (birth control pills);
- alprostadil for erectile dysfunction;
- laxatives used for a long period of time;
- medications for treating asthma, such as *theophylline or salbutamol*;
- medications for preventing gout (*probenecid*);
- medications for treating gastric acidity (*aluminum phosphate*);
- medications or dietary supplements containing *liquorice root*;
- medications for muscle relaxation (*muscle relaxants*);

If you are going to undergo a procedure involving curare-like muscle relaxants (for example, *vercuronium*) or anesthesia, tell the anesthesiologist/dentist that you are using this medication.

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you might be pregnant, or plan to become pregnant, consult your doctor or pharmacist for recommendations before taking this medication.
This medication may only be used on the recommendation of a doctor for pathological edema during pregnancy, and only if the maternal therapeutic benefit justifies the potential risk to the fetus.

Driving and using machines
Do not drive or operate machinery if you feel less alert after taking Furosemid Slavia.

Furosemid Slavia contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Furosemid Slavia

Always take this medicine exactly as your doctor or pharmacist has told you. Discuss with your doctor or pharmacist if you are not sure.
Tablets should be swallowed whole, not chewed, with a glass of water.

The doses and mode of administration should be adjusted according to the severity of the condition. The lowest effective dose should be used to achieve the desired effect. Your doctor will determine the dose and duration of treatment.

Adults

Edema from heart failure
The recommended initial dose is 20 - 80 mg of furosemide, taken orally. This may be adjusted according to therapeutic response. It is recommended that the daily dose be divided into 2 - 3 doses.

Edema from liver cirrhosis
Furosemide is used as additional treatment to aldosterone antagonists when their effect alone is not sufficient. The recommended initial dose is between 20 mg - 80 mg per day, taken orally. This may be adjusted according to therapeutic response as necessary. The daily dose may be taken in one or more doses.

Edema associated with renal failure

The recommended initial dose is between 40 mg - 80 mg per day, taken orally. This may be adjusted according to therapeutic response as necessary. The dose may be increased by 80 mg of furosemide per day until optimal response is achieved. The total daily dose may be taken in one or two doses.

For patients undergoing dialysis, the usual maintenance dose for oral administration is 250 mg - 1500 mg per day. Sometimes higher doses are required in renal failure: 500 - 1000 mg of furosemide per day.

Edema from nephrotic syndrome
The recommended initial dose is 40 mg - 80 mg per day, taken orally. This may be adjusted according to therapeutic response as necessary. The total daily dose may be taken in one or more doses.

High blood pressure
The recommended initial daily dose is 20 mg of furosemide, taken in the morning. If there is an inadequate response, the daily dose may be increased to 40 mg of furosemide, or furosemide may be combined with another antihypertensive.

Use in children and adolescents
For children over 6 years old, the usual recommended dose is 1 - 2 mg of furosemide per kg per day. If there is an inadequate therapeutic response, the dose may be increased by 1-2 mg/kg, but not earlier than 6-8 hours after the previous administration. Doses higher than 6 mg/kg per day are not recommended.

If you take more Furosemid Slavia than you should
If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital immediately. Always take the medicine box with you, so that the specialized staff knows what you have taken. Symptoms of an overdose include dehydration and changes in the levels of certain chemicals in the blood.

If you forget to take Furosemid Slavia

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

If you stop taking Furosemid Slavia
Take Furosemid Slavia for the whole period of treatment set by your doctor, even when you start to feel better.
If you have any further questions on 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.
The following adverse reactions have been reported when taking furosemide:

Very common (may affect more than 1 in 10 people):

- disorders of ion concentrations (sodium, potassium, chloride, calcium and magnesium) in the body, with the following manifestations: dry mouth, fatigue, dizziness, muscle pain or cramps, irregular heartbeats, general feeling of unwellness;
- dehydration and reduction in blood volume in the body (hypovolemia), especially in elderly patients;
- increase in blood creatinine levels;
- increase in the concentration of a type of fats in the blood (triglycerides);
- decrease in blood pressure (hypotension), sometimes only upon standing up from a lying or sitting position (orthostatic hypotension).

Common (may affect up to 1 in 10 people):
- increase in the concentration of a type of fat in the blood (cholesterol);

- increase in the concentration of uric acid in the blood, sometimes accompanied by joint pain (gout attacks);
- impairment of brain function in patients with severe liver dysfunction.

Uncommon (may affect up to 1 in 100 people):

- altered glucose tolerance;
- nausea;
- deafness (sometimes irreversible);.
- skin itching;
- urticaria;
- transient skin rashes;
- severe skin eruptions accompanied by peeling, exfoliation, blistering, and pain (bullous dermatitis, polymorphic erythema, pemphigoid, exfoliative dermatitis);
- appearance of red-purple spots on the skin (purpura);
- increased skin sensitivity to light;
- decrease in the number of blood cells responsible for its clotting (thrombocytopenia).

Rare (affects less than 1 in 1000 users):
- inflammation of small blood vessels (vasculitis);
- renal tissue impairment (tubulointerstitial nephritis);
- vomiting;
- diarrhea;
- ringing in the ears;
- severe allergic reactions (anaphylactic or anaphylactoid);
- numbness or tingling in the hands and feet (paresthesia);
- decrease in the number of white blood cells responsible for fighting infections (leukopenia);
- increase in the number of a particular type of white blood cells (eosinophilia);
- fever.

Very rare (affects less than 1 in 10000 users):
- significant decrease in the number of multiple types of white blood cells (agranulocytosis);
- decrease in the number of red blood cells (anemia);
- impairment of liver metabolism (cholestasis);
- increase in the concentration of liver enzymes (transaminases);
- inflammation of the pancreas (acute pancreatitis).

Frequency unknown (cannot be estimated from available data):
- increased blood glucose levels;
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption);
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension).

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

Adverse reactions reporting
If you manifest any adverse reaction, address your physician or pharmacist. Those can be any adverse reactions not mentioned in this package leaflet. Also, you can report the adverse reactions directly through the national reporting system, that has the details published on the National Agency of Medicines and Medical Devices of Romania http://www.anm.ro/.
By reporting the adverse reactions, you can contribute in providing the additional information regarding this medicine's safety.

5. How to store Furosemide

Keep this medicine out of the sight and reach of children.
Store below 25°C, in the original packaging.

Do not use this medicine after the expiration date printed on the box after EXP.
The expiration date refers to the last day of that month.

EXPIRED AND/OR UNUSED MEDICINES MUST BE RETURNED TO PUBLIC OR PRIVATE HOSPITALS

Do not throw any medicine into the water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Furosemid Slavia contains
- The active substance is furosemide. Each tablet contains 40 mg of furosemide.
- The other ingredients are: maize starch, lactose monohydrate, povidone K30, talc, magnesium stearate.

What Furosemide looks like and contents of the pack

Furosemid Slavia is presented as uncoated tablets, white to slightly yellowish, with a score line on one of the surfaces, with a diameter of 7 mm.
It is available in the following types of packaging:
- box with 2 PVC/Al blisters of 10 tablets each
- box with 10 PVC/Al blisters of 10 tablets each
- box with 100 PVC/Al blister of 10 tablets each

Marketing Authorisation Holder and Manufacturer

Marketing Autorisation Holder
S.C. Slavia Pharm S.R.L.
44C Theodor Pallady Bvd.
3rd District, Bucharest,
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Manufacturer
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