

PACKAGE LEAFLET: Information for the patient

FUROSEMID

Tablets – 40 mg

Solution for injection – 20 mg / 2 ml

(Furosemide)

Read 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 signs of illness 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.

What is in this leaflet:

1. What Furosemid is and what it is used for
2. Before you take Furosemid
3. How to take Furosemid
4. Possible side effects
5. How to store Furosemid
6. Other information

1. WHAT FUROSEMID IS AND WHAT IT IS USED FOR

Furosemid is a diuretic with rapid action. It inhibits the reabsorption of sodium and chloride ions in the proximal and peripheral tubules of the loop of Henle and as a result, sodium, chloride and water excretion is increased. Urinary excretion of potassium, calcium, magnesium and bicarbonates is also enhanced, while urine pH increases.

Furosemid is indicated in:

- oedemas which happen in congestive heart failure, hepatic cirrhosis, kidney diseases, including nephrotic syndrome;
- localised oedemas (post-traumatic or due to burns).

Furosemid solution for injection is also indicated:

- in acute pulmonary oedemas;
- for the treatment of oliguria, due to renal failure.

Furosemid is efficient in the treatment of hypertension, alone or combined with other antihypertensive drugs. Furosemid is a potent diuretic, with a rapid action and is also especially important in patients where other less potent diuretics, like thiazide diuretics, do not function properly.

Your doctor may have given Furosemid for another purpose. Ask your doctor if you want to know why you have been given Furosemid.

2. BEFORE YOU TAKE FUROSEMID

Do not take Furosemid if:

- you are allergic to furosemide, to other diuretics, or to any other excipient of Furosemid products. Patients allergic to sulphonamides (e.g. sulphonylurea derivatives, sulfonamide antibiotics) may manifest cross - sensitivity to furosemide;
- you suffer from anuria;
- you suffer from renal failure due to nephrotoxic or hepatotoxic drugs;
- you suffer from renal failure, accompanied with hepatic coma;
- you are in comatose or pre - comatose condition which accompanies hepatic cirrhosis;
- you have severe hypopotassemia or hyponatremia.

If you think that you have any of the above-mentioned conditions, do not take the drug. Talk initially to your doctor and follow the given advices.

Take special care with Furosemid:

Inform your doctor if:

- you are or have planned to get pregnant during the time you are using Furosemid;
- you are taking other diuretics or you are doing a diet with potassium restriction, because patients that are being treated with furosemide should take an adequate amount of potassium, through a diet rich in potassium (dry fruits, potatoes, tomatoes) or with medication (potassium chloride);
- you are diabetic and use insulin; glucose blood concentrations should be carefully monitored, because insulin needs may change;
- you have hypovolemia and hypotension; electrolyte level should be monitored during treatment with Furosemid;
- you have hypoproteinemia;
- you have gout;
- you suffer from prostatic hypertrophy or impairment of micturition.

Taking other medicines

Ask your doctor or pharmacist if you are taking or have recently taken other drugs, including those without a prescription.

Furosemid and the loop diuretics in general may affect the effect of the following drugs:

- aminoglycosides (furosemide may increase the ototoxicity of the aminoglycosidic antibiotics like gentamicin, kanamycin, neomycin and streptomycin, and also the nephrotoxicity of cephaloridine; aminoglycosidic antibiotics and furosemide, especially when the last one is administered parenterally, should not be concomitantly used);
- chloral hydrate;
- digitalic glycosides (as a result of significant loss of potassium, in patients who use digitalic glycosides, toxicity from these glycosides may appear);
- lithium carbonate;
- non-depolarising neuromuscular blockers (furosemide may increase the effects of tubocurarine and of the other non-depolarising neuromuscular blockers);
- propranolol;
- sulfonyleureas;

- theophylline.

The effect of furosemide and of the other loop diuretics may be affected by:

- carbon;
- cisplatin;
- clofibrate;
- hidantoins;
- non-steroidal anti-inflammatory drugs (i.e. the concomitant use of indomethacin and furosemide may reduce the natriuretic and antihypertensive effects of the last one);
- probenecid;
- salicylates (the toxic effect of salicylates may appear even in small doses of furosemide);
- thiazide diuretics.

These drugs may be affected by Furosemid or may affect the way it acts. So during their concomitant use, the amount of furosemide may be increased or decreased. Your doctor or pharmacist will advise you.

Taking Furosemid with food and drinks

Food does not affect furosemide absorption. There are also no data that demonstrate that Furosemid interacts with alcohol.

Pregnancy

Ask your doctor or pharmacist if you are pregnant or you are planning to become pregnant.

Furosemide is not recommended to be used in pregnancy. Your doctor or pharmacist will discuss on the risks or benefits of its administration during pregnancy.

Breastfeeding

Ask your doctor or pharmacist if you breastfeed the baby with breastmilk because mothers that breastfeed babies should not use Furosemid.

Driving and using machines

There are no data that this drug may affect your ability to drive and use machines.

Important informations about some of the excipients of Furosemid

For the tablet

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

3. HOW TO TAKE FUROSEMID

Always take Furosemid tablets exactly as your doctor has told you. If you feel that the effects of Furosemid are too strong or too weak, talk to your doctor or pharmacist.

Furosemid 40 mg tablets:

In edemas: initially are taken 40 mg in the morning; the maintenance dose is 20 mg daily or 40 mg on alternate days; in resistant edemas the dose may be increased to 80 mg daily.

Children: 1 - 3 mg / kg weight daily, maximum 40 mg daily.

In hypertension: are taken 40 - 80 mg daily, alone or with other antihypertensives.

In oliguria: initially are used 250 mg daily; if necessary higher doses can be used, that are increased gradually in 250 mg, every 4 - 6 hour, until a maximum single dose of 2 g (rarely used).

It is recommended that the tablets should be taken at the same time every day. Furosemid tablets should be swallowed whole, with a glass of water.

Furosemid 20 mg / 2 ml solution for injection:

Intramuscular injection or with slow intravenous injection (with a rate that does not exceed 4 mg / minute): initially are used 20 - 50 mg.

Children: 0.5 - 1.5 mg / kg weight, until a maximum daily dose of 20 mg.

Intravenous perfusion:

In oliguria: initially are used 250 mg for 1 hour (the rate should not exceed 4 mg / minute); if a satisfactory urine excretion is not achieved in the following hour, 500 mg for 2 hours may be

used and then if the urination is not satisfactory in the following hour, 1000 mg for 4 hours may be used and if the right result is not achieved, dialysis may be necessary. The effective dose (up to 1000 mg) may be repeated every 24 hours.

Your doctor may ask you to take Furosemid for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Furosemid than you should

If you take more Furosemid or if the children have taken this drug by mistake, please contact your doctor, hospital or call the emergency to take an opinion for the risk and advice for the actions to be taken.

If you forget to take Furosemid

If you forget a dose, take the following dose when it is time to take the usual dose.

Do not take a double dose to make up for the forgotten dose. If you have any other questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time not. Do not get alarmed by this list of possible side effects. You may not get any of them.

Ask your doctor if any of the following side effects bothers you:

- electrolyte and fluid imbalance, especially when high doses are used, or when the treatment continues for a long time. Significant diuresis may cause dehydration and decrease of blood volume, with circulation disorders, especially in elderly patients;
- hyponatremia, hypochloremic and hypokalemic alkalosis;
- gastrointestinal disorders (nausea, diarrhea);
- allergy;
- rash;
- changes in blood components (thrombocytopenia, agranulocytosis, leucopenia, aplastic anaemia);

- tinnitus and temporary deafness, especially during high doses taken parenterally and in patients with renal function impairment;
- hyperuricemia, glucosuria and hyperglycaemia;
- hypocalcaemia (rare cases of tetanus are described).

Other relatively very rare adverse effects are:

- blurred vision, dizziness, headache, pancreatitis, photosensitivity, muscle cramps, postural hypotension, which may be aggravated by alcohol and narcotics;
- paraesthesia and liver impairment.

When adverse effects are moderate or severe, the dose of Furosemid should be lowered or the treatment should be stopped.

If you notice adverse effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE FUROSEMID

Keep away from children.

Do not use Furosemid after the expiry date which is stated on the package.

Store below 25°C.

6. OTHER INFORMATION

What Furosemid 40 mg tablets contain:

The active substance is furosemide.

Each tablet contains 40 mg furosemide.

The excipients are: maize starch, lactose, croscarmellose sodium, povidone, magnesium stearate, talc, sodium starch glycolate.

What Furosemid 20 mg / 2 ml solution for injection contains:

The active substance is furosemide.

Each ampule 2 ml contains 20 mg furosemide (1 %).

The excipients are: sodium hydroxide, sodium chloride and water for injection.

Contents of the pack:

Furosemid 40 mg tablets:

- carton box with 10 tablets;
- carton box with 30 tablets.

Furosemid 20 mg / 2 ml solution for injection:

- carton box with 10 ampules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

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