Package Leaflet: Information for the user

Furosemide 20mg/2ml solution for injection/infusion
furosemide

furosemide

Read all of this 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.
- If you have any further questions, ask your doctor or nurse.
- 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 side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Furosemide is and what it is used for

Furosemide belongs to a group of medicines called diuretics. Furosemide increases the amount of urine produced by your body.

Furosemide is used to relieve symptoms caused when your body contains too much fluid (also called oedema). Too much fluid can be caused by:
- heart problems
- liver problems
- kidney problems

Your doctor has prescribed Furosemide for one of the following reasons:
- When quick and effective removal of excess fluid is needed.
- You are not able to take this kind of medicine by mouth or in an emergency.
- You have too much fluid around your heart, lungs, liver or kidneys.

In periods with extremely high blood pressure that may lead to life-threatening conditions (hypertensive crisis).

2. What you need to know before you use Furosemide

Do not use Furosemide
- if you are allergic to furosemide, or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to sulphonamide antibiotics
- if you are severely dehydrated (you have lost lots of body fluid for example by suffering from severe diarrhoea or being sick)
- if you have kidney failure and are not producing urine, despite treatment with furosemide

- if you have kidney failure as a consequence of poisoning with kidney or liver toxic substances
- if you have very low levels of potassium or sodium in your blood
- if the patient is in a coma caused by liver failure
- if you are breastfeeding

If you are uncertain, whether you can use this medicine or not, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or nurse before using Furosemide

- if you normally have problems passing water due to an obstruction (such as an enlarged prostate)
- if you have diabetes
- if you have a low blood pressure or sometimes have sudden falls in blood pressure (Your blood vessels in your heart or brain are to narrow).
- if you have liver disease (such as cirrhosis)
- if you have kidney problems (such as nephrotic syndrome)
- if you are dehydrated (you have lost body fluids-by suffering from severe diarrhoea or being sick), this might lead to collapse or blood clothing
- if you have gout (painful or inflamed joints) due to high levels of uric acid (by-product of metabolism) in your blood
- if you have the inflammatory disease called "systemic lupus erythematosus (SLE)"
- if you have hearing problems
- if you are using sorbitol (sugar substitute for people with diabetes)
- if you are taking medicines that cause life-threatening irregular heart beat (QT interval prolongation)
- if you are taking lithium
- if you have porphyria (disease where the production of the oxygen binding molecule of the red blood cells is disrupted and urine is purple-coloured)
- if your skin has an increased sensitivity to sunlight (photosensitivity)
- if you are an athlete; this medicine might give a positive result in doping tests
- if you have systemic lupus erythematosus (SLE) - a disease of the immune system which affects skin, bones, joints and internal organs
- if you are elderly, you are on other medications which can cause the drop of blood pressure and you have other medical conditions that are risks for the drop of blood pressure.

If given to premature babies furosemide can cause kidney stones or calcification.
If any of these apply to you, your doctor may want to change your treatment or give you special advice.

While you are using Furosemide, your doctors may recommend regular blood tests of your blood sugar levels or your blood uric acid levels. They will also check your blood levels of important body salts such as potassium and sodium which are particularly important if you are being sick or have diarrhoea.

Other medicines and Furosemide

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines you have obtained without a prescription. This is important because some medicines should not be taken together with Furosemide Fresenius Kabi.

In particular, tell your doctor or pharmacist if you are taking:

- Lithium – for mood disorders, as its effect and side effects may be increased by furosemide. Your doctor will prescribe this medicine to you only if absolutely necessary and he will then check your lithium levels and may change your dose
- Risperidone – used for the treatment of certain psychosis
- Heart medicines, such digoxin; your doctor may need to change your dose
- Any medicines for high blood pressure, including thiazide diuretics (like bendroflumethiazide or hydrochlorothiazide), ACE inhibitors (like lisinopril), angiotensin II antagonists (like losartan) as furosemide may cause your blood pressure to fall too low. Your doctor may need to change your dose of furosemide
- Cholesterol or lipid-lowering medicines like fibrates, such as clofibrate, fenofibrate or bezafibrate, as the effect of furosemide may be increased.
- Diabetes medicines, like metformin and insulin, as your sugar levels may be increased
- Anti-inflammatory medicines, including NSAIDS (like aspirin or celecoxib) as they can reduce the effects of furosemide; high doses of pain killers (salicylates) may increase the side effects of furosemide
- Anti-inflammatory or anti-allergic medicines like corticosteroids, medicines to treat stomach ulcers like carbenoxolone, or laxatives, as in combination with furosemide they will affect your sodium and potassium levels. Liquorice has the same effect as carbenoxolone.Your doctor will check your potassium levels
- Injections given during operations, including tubocurarine, curarine derivates and succinylcholine
- Chloral hydrate - for sleeping problems (in isolated cases, the intravenous administration (injection into a vein) of furosemide in a 24 hour period prior to chloral hydrate administration may lead to flushing, increased sweating, anxiety, nausea, increase in blood pressure and faster heartbeat). Therefore, the simultaneous administration of furosemide and chloral hydrate is not recommended.
- Phenytoin or phenobarbital - for epilepsy, as the effect of furosemide may be decreased
- Theophylline - for asthma, as its effect may be increased by furosemide
- Antibiotics like cephalosporins, polymyxins, aminoglycosides or quinolones or other drugs which may affect your kidneys like immunosuppressants, iodinated contrast media, foscarnet or pentamidine as furosemide can make this worse
- Amphotericin B – used for fungal infections if used for a long time
- Probenecid – used with some other medicines to protect the kidney, as it may reduce the effects of furosemide
- Organoplatins - used in some cancers, as furosemide may increase the side effects of this drugs
- Methotrexate - used in some cancers and for severe arthritis, as it may reduce the effects of furosemide
- Drugs to raise your blood pressure (Pressor amines), as they may not work as well when you take them with furosemide
- Aminoglutethimide – used to suppress corticosteroid production (Cushing´s syndrome), as it may increase the side effects of furosemide
- Carbamazepine – used to treat epilepsy or schizophrenia, as it may increase the side effects of furosemide
- Ciclosporin – used to prevent rejection of transplants, as you are at risk of gouty arthritis (painful joints).
- Drugs that will alter your heartbeat such as amiodarone, sotalol, dofetilide, ibutilide, as their effect may be increased by furosemide
- Medicines used as injections before X-ray examinations
- Levothyroxine - used for thyroid problems

Furosemide with food, drink and alcohol
Food is not expected to influence this medicine when it is given into a vein. You can eat and drink as usual when taking Furosemide. You do not need to change your diet unless suggested by a doctor.

Pregnancy, breast-feeding and fertility
Furosemide should not be used during pregnancy unless there are very good medical reasons for using it.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Furosemide can pass from mother to baby
- So this medicine is only given to pregnant women if absolutely necessary.

Do not use Furosemide if you are breast-feeding
- This is because this medicine passes into breast milk.

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

Driving and using machines
Furosemide may make you less alert than usual. Do not drive or operate machinery as furosemide may reduce mental alertness. (see section 4 "Possible side effects").

Furosemide contains sodium
This medicine contains 3.7 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. What you need to know before you use Furosemide

Always use this medicine exactly as described in this leaflet or as your doctor or nurse have told you. Check with your doctor or nurse if you are not sure. Furosemide is normally given by a doctor or nurse. It is given:
- as a slow injection into a vein (intravenous) or
- exceptionally into a muscle (intramuscular).

Your doctor will decide how much you need, when it is to be given to you and the duration of treatment. This will depend on your age, weight, medical history, any other medicines that you are taking and type and severity of your disease.

General:

- The parenteral administration of furosemide is indicated in cases where oral administration is not feasible is not efficient (for example in case of reduced intestinal absorption) or when a quick effect is required.
- In cases where parenteral administration is used, the switch to oral administration is recommended, as soon as possible.
- To achieve optimum efficacy and suppress counter-regulation, a continuous furosemide infusion is generally to be preferred to repeated bolus injections.
- Where continuous furosemide infusion in not feasible for follow-up treatment after one or several acute bolus doses, a follow-up regimen with low doses given at short

intervals (approx. 4 hours) is to be preferred to a regimen with higher bolus doses at longer intervals.

- Intravenous furosemide must be injected or infused slowly; a rate of 4 mg per minute must not be exceeded and should never be given in association with other medicinal products in the same syringe.

Dose regimen:

Adults:

- In the absence of conditions requiring a reduced dose (see below) the recommended initial dose for adults and adolescents over 15 years, is 20 to 40 mg by intravenous (or in exceptional cases intramuscular) administration; the maximum dose varying according to individual response.
- If your doctor thinks a higher dose is needed, you may be given further 20 mg injections. This is usually given every 2 hours, until the desired fluid loss occurs.
- Larger initial or maintenance doses may be needed in certain circumstances, depending on your medical condition. This will be determined by your doctor. If such doses are needed, they may be given by continuous infusion.

Children and adolescents (up to 18 years of age):
The experience in children and adolescents are limited. The intravenous administration of furosemide to children and adolescents below 15 years is only recommended in exceptional cases.
The dosage will be adapted to the body weight, and the recommended dose ranges from 0.5 to 1 mg/kg body weight daily up to a maximum total daily dose of 20 mg. There should be a switch to oral therapy as soon as possible.

Elderly:
The older people are usually given 20 mg/day at first. This can be gradually increased until the desired fluid loss occurs.

Weight loss by loss of body fluid should not be more than 1 kg of body weight per day.

If you need to keep using Furosemide, your doctor will probably recommend a switch from injections to an oral (tablet) form of this medicine, as soon as possible.

If you use more Furosemide than you should
If you think you have been given too much of this medicine, tell your doctor straight away.
Signs which may occur if you have been given too much of this medicine are dryness of the mouth, increased thirst, irregular heartbeat, mood changes, muscle cramps or pain, feeling or being sick, unusual tiredness or weakness, a weak pulse or loss of appetite.
If you think you have missed an injection, speak to your doctor or nurse.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. The following side effects may occur during treatment with Furosemide:

Common (may affect up to 1 in 10 people)

- hepatic encephalopathy in patients with hepatocellular insufficiency (symptoms include forgetfulness, fits, mood changes and coma)

Uncommon (may affect up to 1 in 100 people)

- Skin rashes (including itching, redness, peeling), a tendency to bruising or your skin being sensitive to sunlight
- Blood cell changes can lead to failure of blood clotting (with increased risk of bleeding)
- Deafness (sometimes irreversible)

Rare (may affect up to 1 in 1,000 people):

- Feeling or being sick, diarrhoea, constipation, loss of appetite, discomfort in the mouth and stomach.
- Hearing problems (more common in with kidney failure) and tinnitus (ringing in the ears).
- Anaphylaxis, a severe allergic reaction which can cause skin rashes, swelling, breathing difficulties, and loss of consciousness. Get medical help **immediately**.
- Kidney damage (interstitial nephritis)
- Very low white blood cell levels in the blood (which can lead to life threatening infections). Get medical help **immediately**.
- Muscle problems, including leg cramps or muscle weakness
- Pain or discomfort where the injection is given (particularly after injection into muscle)
- The inflammatory disease lupus erythematosus may occur or get worse
- Changes in blood test results (fat-like substances in your blood)
- A numb feeling, tingling or feeling dizzy
- High temperature
- Blurred eye-sight, confusion, sleepiness
- Dry mouth

Very rare (may affect up to 1 in 10,000 people):

- Severe muscle problems including twitching, spasms, cramps (also called “tetany”).
- Blood cell changes can lead to anaemia, inability to fight infection
- Pancreatitis (severe tummy pain) due to inflammation of the pancreas

Not known (frequency cannot be estimated from the available data)

- Stevens-Johnson Syndrome (blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever)
- Toxic epidermal necrolysis (layers of the skin may peel off to leave large areas of raw exposed skin all over the body)
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- DRESS (Drug rash with eosinophilia and systemic symptoms)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension or by other causes), headache
- Exacerbation or activation of systemic lupus erythematosus (signs may include rash, join pain, fever)
- Cases of muscle injury (rhabdomyolysis) have been reported, frequently related to severe hypokalemia

The following may also occur:

- Low blood pressure making you feel faint or dizzy. It may also cause the feeling of pressure in the head, joint pain, blood clot formation, or collapse of your circulation (shock)
- Low potassium levels in the blood. This can cause muscle weakness, tingling and numbness, slight inability to move a body part, being sick, obstipation, increased gas in your gut, increased urine production, increased urge to drink, or slow or irregular heart rhythm**.** These problems are more likely if you have other diseases like liver or heart problems or too little potassium in your diet or if you take other medicines (see "Taking other medicines"). Extreme potassium losses can cause a transiently reduced movement of your intestine or a reduced awareness, with deep extended reduced consciousness in extreme cases. Regular blood checks and potassium supplements may be needed
- Low sodium, calcium and magnesium levels in the blood. This may occur due to increased loss of sodium, calcium and magnesium with your urine. Low sodium levels typically cause a lack of interest, cramp in the calf, reduced appetite, weakness, sleepiness, being sick and confusion. Low calcium levels may cause badly cramps of your muscles. These badly cramps of your muscles or an irregular heartbeat can also be caused by low magnesium levels in your body.
- Gout may occur or get worse
- Existing problems passing water may be made worse
- Diabetes may occur or get worse
- Liver problems or changes in the blood may cause jaundice (yellow skin, dark urine, tiredness)
- Reduced volume of body fluid especially in elderly patients. Sever fluid loss may lead to increased concentration of the blood with a tendency for the development of blood clots
- Premature babies may get kidney stones or calcification
- In premature babies the channel between the lung artery and the aorta which is open in the unborn baby might stay open

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For the UK: Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For IE via:
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Keep the ampoules in the outer carton in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of pack and other information

What Furosemide contains:

- The active substance is furosemide.
- The other ingredients are sodium chloride, sodium hydroxide, water for injections.

What Furosemide looks like and contents of the pack:
Furosemide is a clear colourless to almost colourless solution.
The pack may contain 5, 50 or 100 x 2 ml amber glass ampoules containing Furosemide 20 mg/2 ml solution for injection/infusion.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation holder
For UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way,
Manor Park, Runcorn, Cheshire
Wa7 1NT, UK

For IE:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Str. 1
61352 Bad Homburg
Germany

Manufacturer:
LABESFAL – Laboratórios Almiro S.A. (Fresenius Kabi Group)
Lagedo, 3465-157 Santiago de Besteiros
Portugal
Tel: +351 232 831100

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	Furosemide 20 mg/2 ml oplossing voor injectie / solution injectable / Injektionslösung
Czech Republic	Furosemid Kabi
Finland	Furosemide 10 mg/ml injektioneste, liuos
Ireland	Furosemide 20mg/2ml solution for injection/infusion

Poland	Furosemide Kabi
Portugal	Furosemida Fresenius Kabi 20mg/2ml solução injectável
The Netherlands	Furosemide 20 mg/2 ml oplossing voor injectie
Slovakia	Furosemid Kabi 20 mg/ 2 ml , injekcný roztok
Spain	Furosemida Fresenius Kabi 20 mg/2 ml solución inyectable
United Kingdom (Northern Ireland)	Furosemide 20mg/2ml solution for injection/infusion

This leaflet was last revised in 01/2023.

The following information is intended for healthcare professionals only:

Administration
Intravenous administration of furosemide must be slow; a rate of 4 mg per minute must not be exceeded and should never be given in association with other medicinal products in the same syringe.

Intramuscular administration must be restricted to exceptional cases where neither oral nor intravenous administrations are feasible. It must be noted that intramuscular injection is not suitable for the treatment of acute conditions such as pulmonary oedema.

The initial dose recommended for adults and adolescents over 15 years, is of 20 to 40 mg (1 or 2 ampoules) by intravenous (or in exceptional cases intramuscular) administration; the maximum dose varying according to individual response. If larger doses are required, they should be given increasing by 20 mg increments and not given more often than every two hours.

In adults, the recommended maximum daily dose of furosemide is 1500 mg.

Incompatibilities
Furosemide injection may be mixed with neutral and weak alkaline solution with pH between 7 and 10, such as 0.9% sodium chloride and Ringer's lactate solution.

Furosemide should not be mixed with strong acid solutions (pH lower than 5,5), such as solutions containing ascorbic acid, noradrenaline and adrenaline, due to the risk of precipitation.

Product containing visible particles should not be used.

For single use only, discard any remaining contents after use.

Shelf life
Shelf life of the finished medicinal product:
3 years

After first opening: Once opened the product should be used immediately

After dilution:
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 ºC protected from light.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.