

Package leaflet: Information for the user
Furosemide 10 mg/ml Solution for Injection or Infusion
furosemide

The name of your medicine is 'Furosemide 10 mg/ml Solution for Injection or Infusion' but in the rest of the leaflet it will be called "Furosemide Injection 10 mg/ml".

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 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 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 Furosemide Injection 10 mg/ml is and what it is used for
2. What you need to know before you use Furosemide Injection 10 mg/ml
3. How to use Furosemide Injection 10 mg/ml
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1. What Furosemide Injection 10 mg/ml is and what it is used for

Furosemide Injection 10 mg/ml contains the active ingredient furosemide.

Furosemide is one of a group of medicines called diuretics. Furosemide works by helping to produce more urine. This helps to relieve symptoms caused when your body contains too much fluid.

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)

Furosemide injection must only be used under medical supervision.

2. What you need to know before you use Furosemide Injection 10 mg/ml

Do not use Furosemide Injection 10 mg/ml:

- You are allergic (hypersensitive) to Furosemide, or any of the other ingredients of this medicine (see Section 6)
- You are allergic to sulphonamide antibiotics
- You are severely dehydrated (you have lost lots of body fluid for example by suffering from severe diarrhoea or being sick)
- You have kidney failure and are not producing urine, despite treatment with furosemide
- You have kidney failure as a consequence of poisoning with kidney or liver toxic substances
- You have very low levels of potassium or sodium in your blood
The patient is in a coma caused by liver failure
- You are breastfeeding

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

Take special care with Furosemide Injection if:

- You normally have problems passing water due to an obstruction (such as an enlarged prostate)
- You have diabetes
- You have low blood pressure or sometimes have sudden falls in blood pressure (your blood vessels in your heart or brain are too narrow).
- You have liver disease (such as cirrhosis)
- You have kidney problems (such as nephrotic syndrome)
- You are dehydrated (you have lost body fluids by suffering from severe diarrhoea or being sick), this might lead to a collapse or blood clotting
- You have gout (painful or inflamed joints) due to high levels of uric acid (a by-product of metabolism) in your blood
- You have an inflammatory disease called “ systemic lupus erythematosus (SLE)”
- You have hearing problems
- You are using sorbitol (sugar substitute for people with diabetes)
- You have porphyria (disease where the production of the oxygen binding molecule of the red blood cells is disrupted and urine is purple-coloured)
- Your skin has an increased sensitivity to sunlight (photosensitivity)
- 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.

If given to premature babies furosemide can cause kidney stones calcification or a heart defect where the channel between the lung artery and the aorta which is open in the unborn baby stays open (persistence of patent ductus arteriosus).

If any of these apply to you, your doctor may want to change your treatment or give you special advice.

Your doctor may recommend regular blood tests of your blood sugar levels or your blood uric acid levels. They will also check your blood levels for important body salts such as potassium and sodium, which are particularly important if you are sick or have diarrhea

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines you have obtained without a prescription. This is important because some medicines should not be taken together with furosemide solution for injection or Infusion. 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
- Heart medicines, such as digoxin; your doctor may need to change your dose
- Any medicines for high blood pressure, including thiazide diuretics (such as bendroflumethiazide or hydrochlorothiazide), ACE inhibitors (such as lisinopril), angiotensin II antagonists (such as 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 such as colestyramine, colestipol and fibrates, such as clofibrate, as the effect of furosemide may be reduced
- Diabetes medicines, such as metformin and insulin, as your sugar levels may be increased
- Anti-inflammatory medicines, including NSAIDS (such as 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 such as corticosteroids, medicines used to treat stomach ulcers such as carbenoxolone, or laxatives, as in combination with furosemide they will affect your sodium and potassium levels. Your doctor will check your potassium levels
- Injections given during operations, including tubocurarine, curarine derivatives 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 heart beat). 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 such as cephalosporins, polymyxins, aminoglycosides or quinolones or other drugs which may affect your kidneys such as immunosuppressants, iodinated contrast media, foscarnet or pentamidine as furosemide can make this worse
- 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 drug
- 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
- Sucralfate – used to treat stomach ulcers. Do not take furosemide within two hours of taking sucralfate as the effect of furosemide will be decreased
- Ciclosporin – used to prevent rejection of transplants, as you are at risk of gouty arthritis (painful joints)
 - Drugs that alter your heart beat such as amiodarone, sotalol, dofetilide and ibutilide as their effects may be increased by furosemide.
 - Risperidone – used for the treatment of mental disorders.
 - Other water tablets (diuretics) such as bendroflumethiazide and metolazone
 - Medicines used for thyroid problems such as levothyroxine

Furosemide Injection 10 mg/ml with food, drink and alcohol

Food is not expected to influence this medicine when it is given into a vein. Chronic moderate to heavy drinking raises blood pressure and reduces the effectiveness of antihypertensive drugs. Patients may experience dizziness and fainting shortly after drinking alcohol whilst on treatment.

Pregnancy and breast-feeding:

Furosemide should not be used during pregnancy unless there are very good medical reasons for using it. Furosemide gets into breast milk, and you must not breastfeed while taking it. If you are pregnant or if you are breastfeeding, ask your doctor or pharmacist for further advice before taking furosemide or any other medicine.

Driving and using machines:

Do not drive or operate machinery as furosemide may reduce mental alertness.

Important information about some of the ingredients of Furosemide Injection 10 mg/mlFurosemide 10 mg/ml Solution for Injection or Infusion (2ml, 4ml and 5ml)

This medicinal product contains less than 1 mmol sodium (23 mg) per. ampoule i.e. essentially 'sodium free'. To be taken into consideration by patients on a controlled sodium diet.

Furosemide 10 mg/ml Solution for Injection or Infusion (25ml)

This medicinal product contains approximately 93 mg of sodium per vial. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Furosemide Injection 10 mg/ml

Furosemide Injection is given:

- as a slow injection into a vein (intravenous) or
- in exceptions, 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 or 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 is 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.

Dosage regimen:**Adults:**

- In the absence of conditions requiring a reduced dose (see below) the initial dose recommended for adults and adolescents over 15 years, is of 20 mg to 40 mg furosemide (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 administration is 1500 mg.
- 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):

IE/H/0186/001/II/017, version 01, November 2024

- 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.

Renal impairment:

- In patients with severe impairment of renal function (serum creatinine > 5 mg/dl) it is recommended that an infusion rate of 2.5 mg furosemide per minute is not exceed.

Elderly:

- The recommended initial dose is 20 mg/day, increasing gradually until the required response is achieved.

If you receive more Furosemide Solution for Injection or Infusion than you should

If you are concerned that you may have been given too much furosemide, talk to your doctor or other medicinal staff immediately. 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 miss a dose of Furosemide Solution for Injection or Infusion

If you are concerned that you may have missed a dose, talk to your doctor or other medicinal staff immediately.

While you are receiving Furosemide Solution for Injection or Infusion

If you develop severe allergic reactions, like swelling of your face and/or throat or fever tell your doctor or other medicinal staff immediately.

If you stop using Furosemide Solution for Injection or Infusion

If you stop treatment early before your doctor's recommendation, your heart, lungs or kidneys may be seriously affected by too much fluid.

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

4. Possible side effects

Like all medicines, Furosemide can cause side effects, although not everybody gets them.

Tell your doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment

Very common (affects more than 1 in 10 people):

- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to thickening of the blood or blood clots.

Common (affects less than 1 in 10 people):

- In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.

Rare (affects less than 1 in 1,000 people):

- If you have an allergic reaction. The signs may include difficulty in breathing, swelling, lightheadedness, cold clammy skin, pale skin colour, racing heart beat, and loss of consciousness.
- You bruise more easily, get more infections, feel weak or tired more than usual. Furosemide can affect the number of blood cells, causing serious blood problems.
- Inflammation of your blood vessels (vasculitis). Symptoms may include fever, loss of appetite, weight loss, aches and pains.
- Inflammation of the kidney associated with blood in the urine, fever and pain in the sides (Interstitial nephritis). Rarely could also lead to acute kidney failure.

Very rare (affects less than 1 in 10,000 people):

- Severe stomach or back pain. These could be signs of 'pancreatitis'.

Frequency unknown:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- You find it hard to urinate. This could be a symptom of acute urinary retention.
- You suffer from a kidney disorder where there is an increased amount of calcium in your kidneys. This could be a symptom of nephrocalcinosis.
- You suffer from blood in your urine or pain in your abdomen or groin. This could be a sign of kidney stones (nephrolithiasis).
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.
- You have blood clots, symptoms may include sudden shortness of breath, chest pain, swelling of the leg or arm, leg pain or tenderness, redness or discoloration in the leg or arm, acute changes in eyesight.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).
- Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- You have muscle weakness, tenderness or pain. You may also feel unwell or have a high temperature. You may have something called "rhabdomyolysis". This is a rare but serious illness that may be life-threatening.

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people):

- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure
- Change in the amount of some salts (such as calcium, potassium, magnesium, sodium and chloride) which are needed for your body to work properly. Signs include increased thirst, headaches, low blood pressure, confusion, muscle cramps, muscle weakness, fast or irregular heart rate and stomach upset.

Common (affects less than 1 in 10 people):

- Gout from high levels of uric acid in the blood causing symptoms especially painful inflammation of the joints

Uncommon (affects less than 1 in 100 people):

- Skin rashes, itchy skin, change in skin colour, purple patches like bruising, severe blistering of the skin, target lesions, shedding of skin, and being more sensitive to the sun than usual
- Problems hearing
- Deafness (sometimes irreversible)

Rare (affects less than 1 in 1,000 people):

- Tingling or feeling numb on the skin

Very rare (affects less than 1 in 10,000 people):

- Ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Reduction in blood cells which can cause bruising, make infections more likely, make skin pale yellow or cause weakness or breathlessness (anaemia)

Frequency unknown:

- Change in the levels of some salts (such as sodium or chloride) in the urine
- Dizziness, fainting or loss of consciousness caused by symptomatic hypotension or by other causes), headache.
- Flare up of systemic lupus erythematosus (a condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

Common (affects less than 1 in 10 people):

- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine

Uncommon (affects less than 1 in 100 people):

- Feeling sick (nausea)
- If you have diabetes you may be less able to control the levels of glucose in your blood

Rare (affects less than 1 in 1,000 people):

- Diarrhoea and being sick (vomiting)
- Fever

Very rare (affects less than 1 in 10,000 people):

- An illness where the removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker
- Increase in liver enzymes

Frequency unknown:

- Pain at the site of injection. This occurs when the medicine is injected into the muscle

Blood tests

Furosemide can change the levels of liver enzymes or body fats known as cholesterol and triglycerides.

A blood test may show changes in the way the kidneys are working, indicating a significant reduction in kidney function.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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 Injection 10 mg/ml

Keep out of the sight and reach of children.

Do not store above 25° C.

Do not refrigerate.

Keep the ampoule / vial in the outer carton in order to protect from light.

For single use only.. Use immediately after first opening. Do not use Furosemide Injection 10 mg/ml after the expiry date which is stated on the ampoule and carton after “Exp”. The expiry date refers to the last day of that month.

For storage conditions of the reconstituted/diluted product see: The following information is intended for medical or healthcare professionals only:

Medicine 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. Contents of the pack and other information

What Furosemide Injection 10 mg/ml contains

The active substance is furosemide.

Each ml of solution contains 10 mg of the active ingredient - furosemide.

Each 2 ml sterile solution for injection contains 20 mg of furosemide

Each 4 ml of sterile solution for injection contains 40 mg furosemide.

Each 5 ml of sterile solution for injection contains 50 mg of furosemide.

Each 25 ml of sterile solution for injection contains 250 mg furosemide.

The other ingredients are sodium chloride, sodium hydroxide and water for injections.

What Furosemide Injection 10 mg/ml looks like and the contents of the pack

Furosemide Injection 10 mg/ml is a colourless or almost colourless sterile solution for injection or infusion.

20 mg in 2 ml: amber coloured ampoule with two white ring and white OPC dot containing 2 ml solution.

40 mg in 4 ml: amber coloured 5 ml ampoule with white snap off and blue band containing 4 ml solution.

50 mg in 5 ml: amber coloured 5 ml ampoule with white snap off and white band containing 5 ml solution.

250 mg in 25 ml: Type I amber glass vial sealed with a chlorobutyl rubber stopper and aluminium seal and a red flip off cap containing 25 ml solution.

Pack sizes:

5, 10 x 2 ml ampoules

1, 5,10 x4 ml ampoules

50 mg/ 5 ml; 5, 10 x 5 ml ampoules

1,5,10 x 25 ml vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

IE/H/0186/001/II/017, version 01, November 2024

Marketing Authorisation Holder:

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
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Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
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Name of the Member State	Name of the medicinal product
Austria	Furosemide Accord 10mg/ml Injektionslösung
Belgium	Furosemide Accord 20mg/2ml, 40mg/4ml, 50mg/5ml & 250mg/25ml oplossing voor injectie
Bulgaria	Furosemide Accord 10mg/ml инжекционен разтвор
Cyprus	Furosemide Accord 10mg/ml Solution for Injection
Czech Republic	Furosemid Accord 10mg/ml, injekční roztok
Denmark	Furosemid Accord 10mg/ml Injektionsvæske, opløsning
Estonia	Furosemide Accord
Finland	Furosemide Accord 10mg/ml injektioneste, liuos
Germany	Furosemid Accord 10mg/ml Injektionslösung
Ireland	Furosemide 10mg/ ml Solution for Injection
Italy	Furosemide Accord
Lithuania	Furosemide Accord 10mg/ml injekcinis tirpalas
Netherlands	Furosemide Accord 10mg/ml oplossing voor injectie
Poland	Furosemide 10 mg/ ml Solution for Injection
Portugal	Furosemida Accord
Spain	Furosemida Accord 10mg/ml solución inyectable
Sweden	Furosemid Accord 10mg/ml injektionsvätska, lösning
United Kingdom (NI)	Furosemide 10 mg/ ml Solution for Injection

This leaflet was last revised in: November 2024

The following information is intended for medical or healthcare professionals only:

Any unused solution should be adequately disposed of, in accordance with local requirements.

Handling Instructions

For single use only.

Do not use Furosemide Solution for Injection or Infusion after the expiry date, which is stated on the ampoule and carton after “Exp”. The expiry date refers to the last day of that month.

Furosemide Injection diluted to 1 mg/ml is compatible with 9 mg/ml (0.9%) NaCl Infusion, and Compound Sodium Lactate Infusion for 24 hrs. The dilution of the solution for injection or infusion is to be made under aseptic conditions.

The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Any unused product or waste material should be disposed of in accordance with local requirements. Product containing visible particles should not be used. For single use only, discard any remaining contents after use.

Furosemide 10 mg / ml Solution for Injection or Infusion solution should not be mixed with any other drugs in the injection bottle.

Storage information

Do not store above 25° C.

Do not refrigerate.

Keep the ampoule/ vial in the outer carton in order to protect from light.

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°C protected from light.