**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.

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**What is in this leaflet**



## 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 or calcification.
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 of 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 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 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.

**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/ml**

Furosemide 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 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.

**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 ampules) 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):**

- 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. If you notice any of the following, tell the doctor or nurse immediately:

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

▪ Skin rashes (including itching, redness, peeling), a bruising tendency 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 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. Seek 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 eyesight, confusion, sleepiness.
- Dry mouth.

**Very rare (may affect up to 1 in 10,000 people)**
- Severe muscle problems including twitching, spasms, cramps (also called "tetanus").
- Blood cell changes that 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)**acute generalised exanthematous pustulosis (AGEP)" (acute febrile drug eruption)
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

**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, constipation, 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").
- 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. Cramps can also be associated with low calcium levels or 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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see contact details below).
By reporting side effects you can help provide more information on the safety of this medicine.

**Ireland**
HPRA Pharmacovigilance Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

## 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 contentof 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
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**

**Marketing Authorisation Holder:**

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

**Manufacturer**

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

**This leaflet was last revised in:**

**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 25ºC protected from light.