Package leaflet: Information for the patient

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Furosemide 10 mg/ml solution for injection/infusion

furosemide

Read all of this leaflet carefully before you are given 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.
- 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 Injection is and what it is used for
2. What you need to know before you are given Furosemide Injection
3. How Furosemide Injection is given
4. Possible side effects
5. How to store Furosemide Injection
6. Contents of the pack and other information

1. What Furosemide Injection is and what it is used for

Furosemide Injection contains a medicine called furosemide, belongs to a group of medicines called diuretics (water tablets).
Furosemide Injection can be used to help you lose extra water in your body very quickly. It is given when you cannot take a tablet or when you have a lot of extra water in your body. It is often used when you have too much water around your heart, lungs, liver or kidneys.

2. What you need to know before you are given Furosemide Injection

You must not be given Furosemide Injection:
- If you are allergic to Furosemide Injection or any of the other ingredients of this medicine (listed in section 6). If you are allergic to a group of medicines called sulfonamides (e.g. Co-Trimoxazole, sulfadiazine) or sulfonamide derivatives and amiloride you may also be allergic to this injection.
- If you are dehydrated, your blood volume is low (you may feel dizzy, faint or have pale skin) or you are unable to pass urine.
- If you have low levels of potassium or sodium or an imbalance of chemicals in your blood (shown in a blood test).
- If you have severe liver problems (cirrhosis) that are affecting your consciousness.
- If you previously received certain medicines that have damaged your kidneys or liver.
- If you have already taken furosemide in the past to treat failure to pass urine or kidney failure, or if you have kidney failure due to underlying liver disorders.
- If you have an illness called “Addison’s Disease”. This can make you feel tired and weak.
- If you are taking digitalis preparation/digoxin/cardiac glycosides to treat heart problems.
- If you have a disease called porphyria characterised by abdominal pain, vomiting or muscle weakness.
- If you are breast-feeding.

Warnings and precautions

Talk to your doctor or nurse before you are given Furosemide Injection:
- If you have hypotension (low blood pressure) or feel dizzy when you stand up.
- If you feel dizzy or dehydrated. This can happen if you have lost a lot of water due to being sick, having diarrhoea or passing water very often. It can also happen if you are having problems drinking or eating.
- If you are an elderly patient with dementia and are also taking risperidone.
- If you are elderly, if you are on other medications which can cause the blood pressure to drop and if you have other medical conditions that are risks for the drop of blood pressure.
- If you have (or potentially may have) diabetes.
- If you have gout.
- If you have (or have had) any problems with your liver or kidneys.
- If you have difficulty in passing water, for example because of a large prostate gland.
- If you have low blood protein level (hypoproteinaemia) as this may reduce the effect of the medicine and increase the risk of ear damage.
- If you have raised levels of calcium in the blood.
- If premature infants are intended to be given furosemide as they may be more prone to develop kidney stones and should therefore be monitored closely during treatment.

Do not use Furosemide Injection if you are planning to undergo a procedure that includes the use of radiocontrast (as Furosemide Injection may increase the risk of kidney damage).

Regular monitoring is required including a complete blood count to check for blood dyscrasias (imbalance of blood components) and for blood levels of sodium, potassium, magnesium, calcium, chloride, bicarbonate, kidney function tests (blood urea nitrogen and creatinine levels), glucose and uric acid.

Other medicines and Furosemide Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines as they may interact with your Furosemide Injection:
- Medicines to help your heart beat (e.g. cardiac glycosides like digoxin). Your doctor may need to change the dose of your medicine.
- Medicines to help your heart beat regularly (e.g. amiodarone, flecainide, lidocaine, mexiletine, disopyramide, beta blockers (sotalol)).
- Medicines to lower your blood pressure particularly medicines known as ACE inhibitors (ramipril, enalapril, perindopril), and angiotensin II receptor antagonists (losartan, candesartan, irbesartan), renin inhibitors (aliskiren).
- Other medicines used to lower your blood pressure or for heart problems including diuretics that help you pass more urine (metolazone), calcium channel blockers, hydralazine, minoxidil, thymoxamine, nitrates, prazosin, clonidine, methyldopa, moxonidine, sodium nitroprusside.
- Lithium e.g. used for mental illness.
- Medicines used to treat pain or inflammation (e.g. indometacin, ketorolac, acetylsalicylic acid).
- Antibiotics belonging to the aminoglycoside class, or polymixin class or vancomycin (there may be a risk of ear or kidney damage), or cephalosporins e.g. cephalexin and ceftriaxone. There may be a risk of low sodium levels with trimethoprim.
- Cisplatin used to treat cancer (increased risk of kidney damage).
- Methotrexate to treat cancer, arthritis, psoriasis or other autoimmune diseases - increased risk of furosemide toxicity.
- Ciclosporin to prevent or treat organ rejection after transplantation.
- Aldesleukin to treat kidney cancer.
- Medicines to treat epilepsy e.g. phenytoin, carbamazepine.
- Antihistamines (medicines to treat allergies).
- Corticosteroids to treat inflammation.
- Medicines to relax your muscles like baclofen and tizanidine or curare like drugs.
- Anti-psychotics (medicines to treat mental disorders) (pimozide, amisulpride, sertindol or phenothazines), tricyclic antidepressants and monoamine oxidase inhibitors (medicines to treat depression) hypnotics and anxiolytics (chloral hydrate, triclofos), risperidone to treat dementia, medicines used to treat attention deficit disorder (ADHD) like atomoxetine (increased risk of hypokalaemia and cardiac arrhythmias).
- Medicines used as general anaesthetics to induce unconsciousness.
- Medicines to treat diabetes.
- Antifungals e.g. amphotericin (risk of potassium loss).
- Levodopa used to treat Parkinson’s disease (increased risk of blood pressure drop).
- Birth control pills and oestrogen containing drugs may block the effect of furosemide if taken concurrently.
- Medicines to treat erectile dysfunction like alprostadil.
- Theophylline used for wheezing and breathing difficulties associated with asthma.
- Probenecid used to treat gout.
- Medicines to treat asthma when given in high doses like salbutamol, tertbutaline, salmeterol, formoterol or bambuterol.
- Medicines to treat blocked nose such as ephedrine and xylomethazoline.
- Aminoglutethimide to treat breast cancer.
- Laxatives used to treat constipation e.g. bisacodyl, senna.

Furosemide Injection with food and alcohol

Avoid consumption of alcohol with Furosemide Injection as it may lead to excessive lowering of blood pressure. Liquorice may increase a risk of potassium loss when given with Furosemide Injection.

Pregnancy and breast-feeding

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 being given this medicine. The doctor will then decide if the injection is suitable for you.
Furosemide passes into the milk and may inhibit secretion of milk. Breast-feeding should be avoided while being treated with Furosemide Injection.

Driving and using machines

You should not drive or use machinery if you are affected by the administration of Furosemide Injection.

Furosemide Injection contains sodium

This medicine contains a maximum 100 mg sodium (main component of cooking/table salt) in each 25 ml of solution (a maximum 4 mg sodium per 1 ml of solution). This is equivalent to 5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Furosemide Injection is given

Your nurse or doctor will give you the injection.
Your doctor will decide the correct dosage for you and how and when the injection will be given.
During treatment with Furosemide Injection, your doctor may want you to have blood tests to show if the chemicals and fluids in your body are balanced.
If Furosemide Injection is given to a premature infant then the doctor will monitor the infants kidneys to ensure that Furosemide Injection is not causing any problems.

If you are given more Furosemide Injection than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.
Symptoms of furosemide overdose include: low blood volume (you might feel dizzy, faint, have pale skin), dehydration, thickening of blood, decreased sodium and potassium levels (shown in a blood test).
Severe decrease in blood pressure leading to shock, irregular heartbeat, severe kidney disorder, blood clots, decline in mental function, paralysis with loss of muscle tone, lack of emotions and confusion may occur as a result of fluid loss and chemical imbalance.
When furosemide is given at high doses temporary loss of hearing and gout attack may also appear.
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.

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

Allergic reactions may be severe in nature and may involve (severe) itching, skin rash, nettle rash, (high) fever, difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat, sensitivity to light, red patches on the skin, joint pain and /or inflammation of the eyes, conditions such as “acute generalised exanthematous pustulosis (AGEP)” or DRESS (acute febrile drug eruption) characterised by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin. Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis (also known as Lyell’s syndrome), layers of the skin may peel off to leave large areas of raw exposed skin all over the body.

The following information is intended for healthcare professionals only:

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PREPARATION GUIDE FOR:

Furosemide 10 mg/ml solution for injection/infusion

Furosemide Injection is clear colourless to slightly brownish yellow solution, free from visible particles.

pH 8.0-9.3

For intravenous or intramuscular use.

Incompatibilities

Furosemide should not be mixed with any other medication in the same syringe e.g. furosemide produces a precipitate when mixed with dobutamine, diazepam, doxorubicin, droperidol, gentamicin, glucose, mannitol, metoclopramide, potassium chloride, tetracycline, vincristine and vitamins.
It should not be given during infusion with adrenaline, isoprenaline, lidocaine or pethidine.

Dilution

Furosemide Injection can be diluted with glucose 50 mg/ml (5%), sodium chloride 9 mg/ml (0.9%) or Ringer solution.

Shelf life

Unopened ampoules: 3 years.

Opened ampoules: The product should be used immediately after opening the container.

Prepared infusion solutions:
Chemical and physical in-use stability has been demonstrated in glucose solution 50 mg/ml (5%), sodium chloride solution 9 mg/ml (0.9%) and Ringer solution for 72 hours at 25°C.

- Side effect with frequency not known: Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- Severe upper abdominal pain shifting towards the back. These could be signs of “pancreatitis” (inflammation of the pancreas).
- Signs of kidney inflammation such as blood in the urine, pain in the lower back.
- Acute kidney failure.
- Bruising more easily or bleeding, getting more infections (e.g. sore throat, mouth ulcers, fever), feeling weak or tired more than usual. Furosemide can affect the number of blood cells, causing serious blood problems.
- 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 blood clots (especially in the elderly) or “gout”.
- Signs of metabolic acidosis such as: chest pain, irregular heartbeat, nausea, vomiting, weakness.
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. 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.
- A life-threatening form of unconsciousness.

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

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys.
- A crawling sensation on the skin, itching or tingling without any reason, feeling numb on the skin.
- Small changes in your mood such as feeling agitated or anxious.
- **Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension).** Also headaches, loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure.
- Visual disturbances (blurred vision).
- An inflammation of blood vessels.
- Furosemide can cause an excessive depletion of body fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium) with not known frequency (cannot be estimated from available data):
- Symptoms associated with sodium deficiency include: dizziness, drowsiness, confusion, feeling of weakness, listlessness, loss of appetite, cramp in the calf muscles.
- Symptoms of potassium deficiency include: muscle weakness and inability to contract one or more muscles (paralysis), increased urine excretion, heart problems, in severe cases-intestinal functioning disorders or confusion which can result in coma.
- Symptoms of magnesium and calcium deficiency: increased irritability of muscles, heart rhythm disturbances.

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

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation.
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed.
- If you have diabetes you may be less able to control the levels of glucose in your blood.
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.
- Pain at the site of injection. This occurs when the medicine is injected into the muscle.
- Loss of hearing (**deafness**) which can **sometimes** be **irreversible**.

Blood tests

Furosemide can change the levels of liver enzymes or body fats known as cholesterol and triglycerides but usually they return to normal within 6 months.

Additional side effects in children

Deposits of calcium salts in the kidneys and heart defects like patent ductus arteriosus have been reported in premature babies following treatment with furosemide.

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Injection

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 ampoule or carton. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light.

Do not use this medicine if you notice some visible particles or discolouration in the solution for injection/infusion.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Furosemide Injection contains

- The active substance is furosemide. Each 1 ml of solution contains 10 mg furosemide.
  Each 2 ml of solution contains 20 mg furosemide.
  Each 4 ml of solution contains 40 mg furosemide.
  Each 5 ml of solution contains 50 mg furosemide.
  Each 25 ml of solution contains 250 mg furosemide.
- The other excipients are sodium chloride, sodium hydroxide (for pH-adjustment) and water for injections.

What Furosemide Injection looks like and contents of the pack

Furosemide Injection is clear colourless to slightly brownish yellow solution, free from visible particles.

2 ml, 4 ml, 5 ml or 25 ml solution is supplied in 2 ml, 5 ml and 25 ml amber glass ampoules type I with one point cut (OPC).

The following pack sizes are available for Furosemide Injection:

5 or 10 ampoules in cartons contents 2 ml solution

5 or 10 ampoules in cartons contents 4 ml solution (in 5 ml ampoules)

5 or 10 ampoules in cartons contents 5 ml solution

5 or 10 ampoules in cartons contents 25 ml solution

Not all pack sizes may be marketed.

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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°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.