

PACKAGE LEAFLET: INFORMATION FOR THE USER

FUROSEMIDE 10 mg/ml SOLUTION FOR INJECTION

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 pharmacist 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 pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Furosemide 10 mg/ml Solution for Injection is and what it is used for
2. What you need to know before you take Furosemide 10 mg/ml Solution for Injection
3. How to use Furosemide 10 mg/ml Solution for Injection
4. Possible side effects
5. How to store Furosemide 10 mg/ml Solution for Injection
6. Contents of the pack and other information

1. What Furosemide 10 mg/ml Solution for Injection is and what it is used for

Furosemide 10 mg/ml Solution for Injection contains the active substance furosemide. Furosemide is one of a group of medicines called diuretics (water tablets).

What Furosemide 10 mg/ml Solution for Injection is used for

Furosemide 10 mg/ml solution for 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. Furosemide 10 mg/ml solution for injection is often used when you have too much water around your heart, lungs, liver or kidneys.

How Furosemide 10 mg/ml solution for injection works

Furosemide 10 mg/ml solution for injection works by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

2. What you need to know before you take Furosemide 10 mg/ml Solution for Injection

Do not take Furosemide 10 mg/mL Solution for Injection :

- If you are allergic (hypersensitive) to furosemide or any of the other ingredients of Furosemide 10 mg/ml Solution for Injection (listed in section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- If you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide
- If you have severe liver problems
- If your doctor has told you that you have a low blood volume or are dehydrated

- If you are not passing any water (urine)
- If you have too little potassium or sodium in your blood (shown in blood tests)
- If you are breast-feeding (see “Pregnancy and breast-feeding” section below)

Do not use Furosemide 10 mg/ml Solution for Injection if any of the above apply to you. If you are not sure, talk to your doctor or nurse before being given Furosemide 10 mg/ml Solution for Injection.

Warnings and precautions

Talk to your doctor, or pharmacist or nurse before taking Furosemide 10 mg/ml Solution for Injection

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You are taking an antipsychotic drug called risperidone
- You have low levels of protein in your blood (hypoproteinaemia). This will show in blood tests.
- You suffer from acute porphyria symptoms of which may include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also present along with weakness in arms and legs.
- You have liver or kidney problems
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- You have prostate problems
- You have gout
- You feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- You are going to have a glucose test
- If the person having the medicine is a premature infant. This is due to the possible formation of kidney stones
- You have systemic lupus erythematosus (SLE) - a disease of the immune system which affects skin, bones, joints and internal organs
- If you are elderly, if you are on other medications which can cause a drop in blood pressure and if you have other medical conditions that are risks for the drop of blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before being given Furosemide 10 mg/ml Solution for Injection.

Other medicines and Furosemide 10 mg/ml Solution for Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Furosemide 10 mg/ml solution for injection can affect the way some other medicines work. Also, some medicines can affect the way Furosemide 10 mg/ml solution for injection works. In particular, tell your doctor if you are taking any of the following:

The following medicines can affect the way Furosemide 10 mg/ml solution for injection works and increase the chance of you getting side effects:

- Medicines such as ramipril, enalapril, perindopril (called ‘ACE inhibitors’) or losartan, candesartan, irbesartan (called ‘angiotensin II receptor antagonists’). Your doctor may need to change the dose of your tablets or ask you to stop taking them
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine
- Medicines to help you sleep and relax such as chloral hydrate
- Medicines used as a general anaesthetic for relaxing your muscles during surgery

- Medicines for diabetes. These may not work as well when you are using Furosemide 10 mg/ml solution for injection
- Theophylline – used for wheezing or difficulty in breathing
- Phenytoin – used for epilepsy. This can lower the effect of Furosemide 10 mg/ml solution for injection
- Risperidone – an antipsychotic drug.

The following medicines can increase the chance of side effects when taken with Furosemide 10 mg/ml solution for injection

- Lithium – used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- Cisplatin – used for some cancers
- Digoxin – used for heart problems. Your doctor may need to change the dose of your medicine
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indometacin
- Carbamazepine – used for epilepsy
- Aminogluthetamide – used for breast cancer
- Ciclosporin – used to stop the rejection of organs after a transplant
- Methotrexate – used for cancers of the skin, joint or bowel diseases
- Carbenoxolone and sucralfate – used for ulcers of the foodpipe (gullet)
- Reboxetine – used for depression
- Amphotericin – used for fungal infections if used for a long time
- Corticosteroids – used for inflammation (such as prednisolone)
- Liquorice – often used in cough medicines if taken in large amounts
- Probenecid (used with another HIV medicine)
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins
- Medicines used before X-ray examinations (radiocontrast agents)
- Medicines used for constipation (laxatives) if used for a long time such as bisacodyl or senna
- Medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- Other water tablets (diuretics) such as bendroflumethiazide and metolazone.
- Medicines used for thyroid problems such as leviothroxine

Your doctor may need to change the dose of your medicine

Pregnancy, breast-feeding and fertility

Do not have Furosemide 10 mg/ml Solution for injection if you are pregnant. 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. Do not breast-feed if you are being given Furosemide 10 mg/ml solution for injection. This is because small amounts may pass into the mother's milk. Talk to your doctor before having this medicine if you are breastfeeding or planning to breast-feed.

Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel dizzy or unwell after having Furosemide 10 mg/ml Solution for injection. If this happens, do not drive or use any tools or machines.

Furosemide 10 mg/ml Solution for injection contains

This medicinal product contains less than 1 mmol sodium (=23 mg) per dose, that is to say essentially ‘sodium - free’.

3. How to take Furosemide 10 mg/ml Solution for Injection

Furosemide 10 mg/ml Solution for injection is normally given by a doctor or nurse. This is because it needs to be given as an intravenous infusion (diluted or non diluted) or intramuscular injection. Furosemide 10 mg/ml Solution for injection is only given, when tablets can not be taken.

How much Furosemide 10 mg/ml Solution for injection is given

If you are not sure why you are being given Furosemide 10 mg/ml Solution for injection or have any questions about how much Furosemide 10 mg/ml Solution for injection is being given to you, speak to your doctor or nurse. The usual doses are:

Adults and the elderly

The initial dose is 20mg to 50mg. This will then be gradually increased up to a maximum dose of 1500mg per day. If you are elderly you may be given a lower dose.

Use in children

The usual dose for children ranges from 0.5 to 1.5mg/kg body weight daily up to a maximum total daily dose of 20mg.

If you take more Furosemide 10 mg/ml Solution for Injection than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress, and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine. Having too much Furosemide 10 mg/ml Solution for Injection may make you feel confused, unable to focus, show a lack emotion or interest in anything. You may also have dizziness, lightheadedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of body that is affected). You may also have problems with your kidneys or blood.

If you forget to take Furosemide 10 mg/ml Solution for Injection

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you stop taking Furosemide 10 mg/ml Solution for Injection:

Keep having Furosemide 10 mg/ml Solution for Injection until your doctor tells you to stop.

Blood tests

Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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

- If you have an allergic reaction. The signs may include a rash, joint pain, fever (systemic lupus erythematosus), inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- You bruise more easily, get more infections, feel weak or tired more than usual. Furosemide 10 mg/ml Solution for Injection can affect the number of blood cells, causing serious blood problems.

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 blood clots or 'gout'

Common (affects less than 1 in 10 people):

- 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.

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

- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Inflammation of your blood vessels (vasculitis). Symptoms may include fever, loss of appetite, weight loss, aches and pains.

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

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

Frequency unknown:

- 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
- Acute generalised exanthematous pustulosis (AGEP)" (acute febrile drug eruption)
- 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.
- 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.

Uncommon (affects less than 1 in 100 people):

- 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.

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) or a general feeling of being unwell
- 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)

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

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

Frequency unknown:

- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- Pain at the site of injection. This occurs when the medicine is injected into the muscle

Blood tests

Furosemide 10 mg/ml Solution for Injection 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide 10 mg/ml Solution for Injection

Your doctor or hospital pharmacist will know how to store Furosemide 10 mg/ml Solution for injection. Keep this medicine out of the sight and reach of children.

It should be stored below 25°C and kept in original package in order to protect from light.

Do not use this medicine 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.

This medicine must be kept in the original pack to protect from light.

Your doctor or pharmacist will ensure that Furosemide 10 mg/ml Injection is protected from light once prepared for use.

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 to protect the environment.

6. Contents of the pack and other information

What Furosemide 10 mg/ml Solution for Injection contains

Each ml of solution contains 10 mg of Furosemide as the active substance.

The other ingredients are: Sodium hydroxide, Sodium chloride, Hydrochloric acid, Water for Injections

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

Furosemide 10 mg/ml Solution for Injection is a clear and colourless solution, essentially free from visible particles.

It is available in amber coloured glass ampoules containing 2ml or 5ml of solution.

Each box contains 10 or 25 ampoules.

Not all packs sizes may be marketed.

Marketing Authorization Holder:

<To be completed nationally>

Manufacturer:

UAB Noramed

Meistru 8a, Vilnius, 02189, Lithuania.

Bieffe Medital S.P.A.

Via Nuova Provinciale 23034 Grosotto (SO)

Italy.

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

<name of the member state><name of the medicinal product>

<United Kingdom (Northern Ireland)> <name of the medicinal product>

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Information to health care professionals

Single dose container. Use immediately after first opening.

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.

After dilution

Furosemide 10 mg / ml Solution for 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 but must be used within 24 hours of dilution.

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 user and would not normally be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.