

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**FUROSEMIDE 10 mg/ml SOLUTION FOR INJECTION****Read all of this leaflet carefully before you start using this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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**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 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.

**Furosemide injection must only be used under medical supervision.**

**2. Before you use Furosemide 10 mg/ml Solution for Injection****You should not be given Furosemide 10 mg/mL Solution for Injection if:**

- 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
- You have kidney failure
- You are breastfeeding
- You are in a coma caused by liver failure.

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

**Take special care with Furosemide 10 mg/ml Solution for Injection if:**

- You normally have problems passing water due to an obstruction (such as an enlarged prostate)
- You have diabetes
- You have a 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 collapse or blood clots.
- You have gout (painful or inflamed joints) due to high levels of uric acid (by-product of metabolism) in your blood
- You have the 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)
- You are an athlete; this medicine might give a positive result in doping tests

If given to premature babies furosemide can cause 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.

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

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."

**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 10 mg/ml solution for injection. 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 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
- Medicines for diabetes such as metformin and insulin, as your sugar levels may be increased
- Anti-inflammatory medicines, including NSAIDs (such as diclofenac, ibuprofen, celecoxib), as they can reduce the effects of furosemide; high doses of pain killers such as acetylsalicylic acid (aspirin) may increase the side effects of furosemide
- Corticosteroids (such as glucocorticoids), carbenoxolone (for stomach ulcers) or laxatives, in combination with furosemide will affect levels of potassium in your body. Your doctor will do blood test to check your potassium levels.
- Chloral hydrate (for sleeping problems) – giving furosemide injection at the same time as chloral hydrate is not recommended since side effects such as flushing, increased sweating, anxiety, nausea, increased blood pressure and rapid heart rate may occur.
- Phenytoin or Phenobarbital – for epilepsy, as the effect of furosemide may be decreased; Carbamazepine – used to treat epilepsy or schizophrenia, as it may increase the side effects of furosemide
- Theophylline – for asthma, as its effect may be increased by furosemide
- Medicines which may affect your kidneys such as antibiotics (cephalosporins, aminoglycoside, polymyxins, quinolones), immunosuppressant drugs, foscarnet, pentamidine or iodated contrast media – furosemide may make worse the side effects of these drugs on the kidneys.
- Probenecid – used with some other medicines to protect the kidney, as it may reduce the effects of furosemide
- 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 such as adrenaline, noradrenaline), as they may not work as well when you take them with furosemide
- Aminoglutethimide – used to treat Cushing's syndrome, 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)
- Cisplatin – used in cancer chemotherapy or aminoglycoside antibiotics such as kanamycin, gentamicin and tobramycin, as the side effects of these medicines on hearing (ototoxicity) may be made worse by Furosemide, in particular in patients with kidney problems.
- Drugs that alter your heart rate such as amiodarone, sotalol, dofetilide, ibutilide, as their effect may be increased by furosemide.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, you should ask your doctor or pharmacist for further advice before receiving furosemide or any other medicine. Furosemide should not be used during pregnancy unless there are very good medical reasons for using it. Furosemide passes into breast milk. You should not breast-feed while receiving it.

**Driving and using machines**

The ability to drive or operate machinery can be reduced because of treatment with Furosemide, especially at the start of therapy, when medication is changed or in combination with alcohol. If your mental alertness is affected in any way during treatment with Furosemide, you should not drive or operate machinery.

**Important information about some of the ingredients of Furosemide 10 mg/ml Solution for injection**

This medicinal product contains 0.6 mmol sodium per dose (40 mg). If you are on a controlled sodium diet, make sure the doctor treating you is aware of this.

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

Your medicine is normally given by a doctor or nurse:

- 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, other medicines that you are taking and type and severity of your disease.

**The usual doses are:**

Adults and teenagers over 15 years of age:

- The usual first dose is 20 to 40 mg.
- 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.
- In some cases, instead of injections, your doctor may recommend this medicine is given by continuous infusion into a vein (a drip).

Teenagers less than 15 years of age and children:

- For children (children below 15 will only be treated in exceptional cases), the dose depends on the child's weight. The first dose is 0.5 to 1 mg per kilogram of body weight per day.

**Elderly:**

- The elderly are usually given 20 mg/day at first. This can be gradually increased until the desired fluid loss occurs.

**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.

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

**If you receive 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 stop using Furosemide 10 mg/ml Solution for Injection:**

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 pharmacist.

#### 4. Possible side effects

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

If you notice the following, tell the doctor or nurse immediately:

Anaphylaxis, a severe allergic reaction which can cause skin rashes, swelling of the face, lips, tongue or throat, breathing difficulties, and loss of consciousness. Get medical help **immediately**.

**Uncommon (affects less than 100 patients)**

- 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)

**Rare (affects less than 1 out of 1,000 patients):**

- Feeling or being sick, diarrhoea, constipation, loss of appetite, discomfort in the mouth and stomach.
- Hearing problems and tinnitus (ringing in the ears) particularly in patients with kidney problems
- Kidney damage (interstitial nephritis)
- Very low white blood cell levels in the blood (which can lead to life threatening infections). Get medical help **immediately** if you have notice that you have an increased tendency to get infections or are unable to fight them off in the usual way.
- 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 for cholesterol and triglycerides
- Feeling of numbness or tingling of the skin
- Dizziness
- High temperature
- Blurred eye-sight, confusion, sleepiness
- Dry mouth

**Very rare (affects less than 1 out of 10,000 patients):**

- Severe muscle problems including twitching, spasms, cramps (also called "tetanus").
- Blood cell changes can lead to anaemia, inability to fight infection
- Pancreatitis (severe tummy pain) due to inflammation of the pancreas
- Liver problems or changes in the levels of liver enzymes in the blood which may cause jaundice (yellow skin, dark urine, tiredness)

**The following may also occur:**

- At the initial stage of treatment, 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.
- 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 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
- Reduced volume of body fluid especially in elderly patients. Severe fluid loss may lead to increased concentration of the blood with a tendency for the development of blood clots

**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 any side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland**

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

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

Your doctor or hospital pharmacist will know how to store Furosemide 10 mg/ml Solution for injection. It should be stored below 25°C and kept in original pack to protect from light.

Furosemide 10 mg/ml Solution for Injection should not be used 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 product 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.

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

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#### 6. Further 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 the content 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:**

**Ireland:**

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht, Netherlands

**United Kingdom:**

Baxter Healthcare Limited

Caxton Way

Thetford, Norfolk IP24 3SE

**Manufacturer:**

**For United Kingdom and Ireland:**

**UAB Norameda**

Meistru 8a, Vilnius, 02189, Lithuania.

**Bieffe Medital S.P.A.**

Via Nuova Provinciale 23034 Grosotto (SO)

Italy.

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**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.