

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- 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.
- In this leaflet, Furosemide Injection BP Minijet 10 mg/ml Solution for Injection will be called Furosemide Injection.

In this leaflet:

1. What Furosemide Injection is for
2. Before you are given Furosemide Injection
3. How you will be given Furosemide Injection
4. Possible side effects
5. How to store Furosemide Injection
6. Further information.

1. What Furosemide Injection is for

Furosemide Injection belongs to a group of medicines called sulfonamide diuretics. These work by getting rid of excess fluid from the body by increasing how often you urinate. Many diuretics are tablets to be taken by mouth (orally). Furosemide Injection is used when it is necessary to get rid of excess fluid quickly and oral medicines are not appropriate.

Furosemide Injection is used to treat:

- Too much fluid in the body (oedema) caused by heart failure or lung, kidney or liver problems
- Too much calcium in the body
- Deliberate excretion of fluid (forced diuresis) for treatment of poisoning.

If these conditions are left untreated they can lead to serious problems like heart and lung failure.

2. Before you are given Furosemide Injection

Do not use Furosemide Injection if:

- You are allergic to furosemide or other sulfonamide antibiotics
- You are allergic to any of the other ingredients of Furosemide Injection (listed in section 6)
- You are pregnant, trying to become pregnant or breast feeding
- There is any possibility you could get pregnant whilst using this medicine. However, you may be given this medicine if it could be life-saving
- You have kidney failure
- You are very dehydrated
- You are taking medicines for your heart called cardiac glycosides (e.g. digoxin).

You will not be given Furosemide Injection if you are in a coma due to liver failure.

If any of the above applies to you, do not use this medicine and talk to your doctor or nurse.

Check with your doctor before using Furosemide Injection if:

- You have liver disease
- You have an enlarged prostate gland, or problems passing water
- You have gout
- You have diabetes
- You have porphyria (a blood disorder in which excessive blood pigment, porphyrin is excreted in the urine and you are extremely sensitive to light)
- You are going to have a general anaesthetic.

Taking other medicines

You must not be given Furosemide Injection if you are already taking medicines for your heart called cardiac glycosides (e.g. digoxin).

Tell your doctor if you are taking any of the following medicines:

- Any medicines for your heart
- Any medicines for high or low blood pressure (e.g. pressor amines, nifedipine, propranolol, or lisinopril)
- Any medicines for mouth ulcers (e.g. carbenoxolone or metolazone)
- A medicine for fluid loss called metolazone
- Reboxetine for depression
- Lithium for mental disorders
- Any medicines for epilepsy (e.g. carbamazepine, phenytoin)
- Probenecid for gout
- Amphotericin for fungal infections
- Any antibiotics
- Any medicines designed to block the effect of hormones such as medicines for breast cancer, hypersexuality in men or any oral contraceptive ('the Pill').
- Any medicines to lower high cholesterol or triglycerides (e.g. clofibrate)
- Any corticosteroid medicines
- Any anti-inflammatory drugs for pain (e.g. aspirin)
- Any muscle relaxants (e.g. baclofen, izanidine or curare)
- Sedatives such as chloral hydrate
- Diazoxide used to treat low blood sugar
- Liquorice (often used in cough medicines)
- Long-term use of laxatives for constipation (e.g. bisacodyl, senna)
- Any medicine that may harm your kidneys - furosemide could increase the risk of damage
- You are taking any other medicine, including medicines obtained without a prescription.

If any of the above applies to you talk to your doctor or nurse.

Pregnancy and breastfeeding

Tell your doctor or nurse if:

- You are pregnant, trying to become pregnant or breastfeeding
- There is any possibility you could get pregnant whilst using this medicine

Your doctor will not give you Furosemide Injection if you are pregnant, trying to become pregnant or breastfeeding, unless it is required to save your life.

Your doctor may ask you to stop breastfeeding while you are having this medicine.

Driving and using machines

Furosemide Injection may affect your ability to concentrate. If this happens to you, do not drive or use machinery.

Warnings about the ingredients in Furosemide Injection

This medicinal product contains less than 1 mmol sodium per dose, in other words it is essentially 'sodium-free'.

3. How Furosemide Injection will be given to you

Important: Furosemide Injection will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

You will be given Furosemide Injection by a slow injection into the bloodstream via a vein or muscle.

Adults

- Excess fluid in your body (oedema):
 - The usual starting dose is 20 to 40 mg
 - Your doctor may increase the dose by 20 mg every 2 hours if necessary.
- Fluid in the lungs (acute pulmonary oedema):
 - The usual starting dose is 40 mg
 - Your doctor may increase the dose to 80 mg if necessary.

Adults Continued

- Excess calcium in the blood (hypercalcaemia):
 - Doses range from 20 to 240 mg.
- Deliberate excretion of fluid (forced diuresis):
 - Repeated doses of 20 to 80 mg
 - Your doctor or nurse will also give you fluid to replace what you lose.

Children

- The usual starting dose is 0.5 to 1.5 mg per kg of bodyweight
- Your doctor may increase the dose to 1 mg per kg of bodyweight every 2 hours if necessary
- The maximum dose is 6 mg per kg of bodyweight.

Patients with kidney failure

- The usual starting dose is 250 mg given as an infusion (a drip) over 1 hour
- If necessary, your doctor may try a second infusion of 500 mg given over 2 hours
- If necessary, your doctor may try a third infusion of 1000 mg given over 4 hours
- If the third infusion does not work, you will probably be given dialysis.

The total dose you will be given and the duration of treatment depends on your response to the initial and subsequent doses. If you require continued medicine to lose fluid, your doctor will move you onto tablets as soon as possible.

If you think you have been given more Furosemide Injection than you should

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too little or too much. However, tell your doctor or nurse if you have any concerns.

The effects of an overdose are dehydration (excess loss of water and salts from the body) extreme thirst, dark yellow urine, cramps in the arms and legs, dry mouth, dry tongue; with thick saliva. In severe cases, effects include shock, unconsciousness, rapid and deep breathing life-threatening heart failure.

4. Possible side effects

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

Seek immediate medical help if you have any of the following symptoms:

- If you get a rash or easy bruising; you should also **stop using Furosemide Injection immediately**. You may have very low numbers of white blood cells (a serious condition known as agranulocytosis)
- **Swelling of hands, feet, lips, mouth, tongue or throat, difficulty breathing, itchy skin rash, fever, diarrhoea, stomach pains, feeling faint and unconsciousness.** You may have a severe and sometimes life-threatening allergic reaction
- **Anxiety, restlessness, a weak pulse, cool and clammy skin, rapid and shallow breathing, thirst and dry mouth and tiredness.** You may be in shock. This can lead to your blood becoming thicker and the formation of life-threatening clots, particularly if you are elderly.

Other side effects

- Heart palpitations
- Feeling weak and tiredness. This may be a sign of inflamed arteries or veins or low numbers of red blood cells (anaemia)
- Bleeding or bruising easily. This may be a sign of low numbers of blood cells called platelets
- Light headedness or dizziness
- Pains in your muscles
- Feeling thirsty
- Increased sweating

- Passing water more often
- Decreased passing of water in men with prostate disease
- Pain at the site of injection
- Blood clots causing local pain and possible swelling
- Itching, red and swollen skin and peeling skin
- Tingling and burning feeling on the skin
- Blurred vision
- Feeling or being sick
- Diarrhoea
- Difficulty hearing or ringing in the ears. Hearing problems occur more commonly in patients with kidney disease also on treatment with other drugs.

Other rare side effects

- A sweet taste
- Burning feeling in the mouth and stomach
- Swellings
- Headache
- Yellowing of the skin and whites of the eyes (jaundice)
- Severe stomach pain and kidney stones in premature infants
- Gout.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Injection

Keep out of the reach and sight of children.

Do not use Furosemide Injection after the expiry date on the carton and vial label. The expiry date refers to the last day of that month. Do not store above 25°C. Keep the vial in the outer carton. The solution in the vial should only be used once and any remaining contents safely disposed of.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. Further information

What Furosemide injection contains

The active substance is furosemide. Each vial contains 10 mg furosemide in every ml of liquid.

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

What Furosemide Injection looks like

Furosemide Injection is a sterile solution for injection. It is a clear, colourless liquid.

Furosemide Injection comes in a small glass container (vial). Each vial contains 8 ml of solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder

DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland

Manufacturer

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

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