Furosemide Injection

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

Furosemide Injection is a powerful, quick acting diuretic which causes the body to increase the production of urine. It is used to:

• Remove large amounts of fluid that has accumulated in the tissues and lungs (oedema)
• Treat high blood pressure in emergencies
• Increase the production of urine in kidney failure.

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

You should NOT be given Furosemide Injection if:

• You are allergic to Furosemide Injection or any of the other ingredients of this medicine (see section 6). If you are allergic to a group of drugs called xanthines (e.g. theophylline, sulfadiazine) or sulfonamide derivatives and amiodone you may also be allergic to this injection.
• You are dehydrated, your blood volume is low (you feel dizzy, faint or have pale skin) or you are unable to pass urine.
• You have low levels of potassium or sodium or an imbalance of chemicals in your blood (shown in a blood test).
• You have severe liver problems (cirrhosis).
• You have an illness characterised by abdominal pain, vomiting or muscle weakness.
• You are breast-feeding.

Warnings and precautions

Talk to your doctor or nurse before being given the Furosemide Injection if:

• You are pregnant or breast-feeding.
• You have any further questions, ask your doctor or nurse.
• 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.

3. How to store Furosemide Injection

• Keep the 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.

4. Possible side effects

• Medications to help your heart beat (e.g. cardiac glycosides like digoxin). Your doctor may need to change your dose of medication.
• Medications to help your heart beat regularly (e.g. ACE inhibitors, lidocaine, disopyramide, beta blockers (beta-blockers)).
• Medications to lower your blood pressure characteristic (medications to ACE inhibitors (ramipril, enalapril, perindopril), and angiotensin II receptor antagonists (losartan, candesartan, irbesartan).
• Alcohol may increase a risk of hypokalaemia and cardiac arrhythmias.

5. How to use Furosemide Injection

• Avoid alcohol and smoking which can cause the blood pressure to drop and if you have other medical conditions that are risks for the drop of blood pressure.
• You have (or potentially may have) diabetes.
• You have gout.
• You have (or have had) any problems with your liver or kidneys.
• You have difficulty in passing water, for example because of a large prostate gland.
• You have low blood protein level (hypoproteinaemia) as this may reduce the effect of the drug and increase the risk of ear damage.
• You have raised levels of calcium in the blood.
• Premature infants are intended to be given furosemide as they may be 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 cardiac surgery. If you are allergic to 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.

6. Driving and using machines

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

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 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 Injection can harm the baby and may inhibit secretion of milk. Hence it should be avoided in breast feeding women.

7. Overdosing

If you overdose on Furosemide Injection, you should instruct your doctor or pharmacist on how to proceed.
Dizziness, fainting and loss of consciousness

A crawling sensation on the skin, itching or

Problems hearing or ringing in the ears (tinnitus).

Tell your doctor as soon as possible if

- medical treatment

- you may need urgent

cause side effects, although not everybody gets

loss of hearing and gout attack may also appear.

shock, irregular heartbeat, severe kidney disorder, (in a blood test).

If you think you have been given more

Furosemide Injection contains a maximum of 4 mg of furosemide ml. To be taken into consideration by patients on a controlled sodium diet.

3. How Furosemide Injection is given to you

Furosemide Injection contains only 4 mg of furosemide ml. It is given in the form of single injection. Your doctor will decide the correct dose 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 or neonate, the doctor will monitor the infant's kidneys to ensure that the Furosemide Injection is not causing any problems.

If you think you have been 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 should tell the person giving the injection. Symptoms of furosemide overdose include: low blood pressure (you might sense fainting, 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, heart problems, bleeding from the skin, clouding of vision, blurred vision, deafness, difficulty in hearing.

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, cough, feelings of tightness in the chest, pale skin, pale lips, fast and racing heart beat, sensitivity to light, red patches on the skin, joint pain and stiffness, blurred vision or loss of the eyes, conditions such as "acute generalised exanthematous pustulosis (AGEP)" (acute febrile drug eruption) characterised by severe acute (allergic) reaction accompanied by fever, muscle or joint changes, skin blisters, tiny spots from bleeding in the skin.

Blood clots forming while the body is moving around the limbs, eyes, mouth, nose and genitals, flu-like symptoms and fever could be a condition called Stevens-Johnson syndrome. In a milder form of the condition 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.

- severe upper abdominal pain shifting towards the back.

This could be signs of "pancreatitis" (inflammation of the pancreas).

- Signs of kidney inflammation such as blood in the urine in the lower back.

- acute kidney failure.

- Bruising more easily or bleeding, getting more infrequent bruises (e.g. more frequent nose bleed), feeling weak or tired more than usual. Furosemide can affect the chemical balance in the kidney cells, causing serious blood problems.

- Increased thirst, headache, feeling dizzy or light headed, difficulty in swallowing, joint pain 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, bone pain, 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 may have liver problems, an additional liver problem known as liver encephalopathy may occur. Symptoms include: confusion, fits, mood changes and coma.

- A potentially dangerous 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 may affect people who already have problems with their kidneys.

- A craving 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, tiredness and loss of consciousness (caused by symptomatic hypotension). Also headaches, loss of consciousness, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood sugars.

- 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) with not known consequences (cannot be estimated from available data):

- Symptoms associated with sodium deficiency – dizziness, drowsiness, confusion, feeling of weakness, listlessness, loss of appetite, fever or rash in the skin.

- Symptoms of potassium deficiency include: muscle weakness and inability to contract one or more muscles (paralysis), increased urine excretion, heart problems, in severe cases: neurological disorders or confusion which can result in coma.

- Symptoms of magnesium and calcium deficiency: increased immobility of muscles, heart arrhythmia.

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 other side effects not listed in this leaflet

- Rash (acne), a general feeling of being unwell, diarrhoea and being sick (vomiting) and constellation.

- 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.

- Pasting more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

- Pain of injection. This occurs when the medicine is injected into the muscle.

- Liver problems (jaundice) 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 paediatric population

Deposited 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, tell your doctor, nurse or pharmacist.

Reporting of side effects

If you think you have been given more than the prescribed dosage, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. If you think any side effect report side effects directly via the Yellow Card Scheme – website: www.mhra.gov.uk/ yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

What Furosemide Injection contains

The active substance is furosemide. Each 1 ml of solution contains 10 mg furosemide in a sterile solution for injection.

In addition to furosemide: sodium chloride, sodium hydroxide and sterile water for injection.

What Furosemide Injection looks like and contents of the pack

Furosemide Injection is supplied in 2 x 5 ml, 5 ml and 25 ml amber glass ampoules. The injection solution comes as ampoule sizes may be marketed.

The marketing authorisation number of this medicine is: PL 01502/0032.

Marketing Authorisation Holder:

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This leaflet was last revised in 05.2017.

44114/18/17