

**Furosemide 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 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 Furosemide Injection is given to you
3. How Furosemide Injection is given to you
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 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 (listed in section 6). If you are allergic to a group of drugs called sulfonamides (e.g. Co-Trimoxazole, sulfadiazine) or sulfonamide derivatives and amiloride you may also be allergic to this injection.
- You are dehydrated, your blood volume is low (you may 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) that are affecting your consciousness.
- You previously received certain medicines that have damaged your kidneys or liver.
- 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.
- You have an illness called 'Addison's Disease'. This can make you feel tired and weak.
- You are taking digitalis preparation/digoxin/cardiac glycosides to treat heart problems.
- You have a disease called porphyria 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 have hypotension (low blood pressure) or feel dizzy when you stand up.
- 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.
- You are an elderly patient with dementia and are also taking risperidone.
- 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.
- 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 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, methylodopa, 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 polymyxin 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 - increased risk of furosemide toxicity.
- Ciclosporin and aldesleukin.
- 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, sertindole or phenothiazines), tricyclic antidepressants and monoamine oxidase inhibitors (medicines to treat depression) hypnotics and anxiolytics (chloral hydrate, triclofos), risperidone to treat dementia, drugs 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, terbutaline, salmeterol, formoterol or bambuterol.
- Medicines to treat blocked nose such as ephedrine and xylometazoline.
- 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. Hence it should be avoided in breast feeding women.

**Driving and using machines**

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

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

**3. How Furosemide Injection is given to you**

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 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 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.

#### **4. Possible side effects**

Like all medicines, Furosemide Injection 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.

- 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.
- Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- 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 paediatric population**

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

#### **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 – website: [www.mhra.gov.uk/yellowcard](http://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 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.

Your injection will be stored at less than 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 in a sterile solution for injection.
- The other excipients are: sodium chloride, sodium hydroxide and sterile water for injections.

##### **What Furosemide Injection looks like and contents of the pack**

Furosemide Injection is supplied in 2 ml, 5 ml and 25 ml amber glass ampoules. The injection is supplied in cartons of 10 ampoules. Not all ampoule sizes may be marketed.

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

##### **Marketing Authorisation Holder:**

hameln pharma ltd  
Nexus, Gloucester Business Park  
Gloucester, GL3 4AG  
United Kingdom

##### **Manufacturer:**

Siegfried Hameln GmbH  
Langes Feld 13, 31789 Hameln, Germany  
hameln rds s.r.o.  
Horná 36, 900 01 Modra, Slovak Republic  
HBM Pharma s.r.o.  
03680 Martin, Sklabinská, Slovak Republic  
Zakłady Farmaceutyczne POLPHARMA S.A.  
ul. Pelplińska 19, 83-200 Starogard Gdański,  
Poland

**For any information about this medicine, please contact the Marketing Authorisation Holder.**

This leaflet was last revised in 12.2023.

## Package leaflet: Information for the patient

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- You are an elderly patient with dementia and are also taking risperidone.
- 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.
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- Lithium e.g. used for mental illness.
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- Aminoglutethimide to treat breast cancer.
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#### 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. Hence it should be avoided in breast feeding women.

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

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#### 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 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.

#### 4. Possible side effects

Like all medicines, Furosemide Injection 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**

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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.

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#### **Blood tests**

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##### **What Furosemide Injection looks like and contents of the pack**

Furosemide Injection is supplied in 2 ml, 5 ml and 25 ml amber glass ampoules. The injection is supplied in cartons of 10 ampoules. Not all ampoule sizes may be marketed.

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

##### **Marketing Authorisation Holder:**

hameln pharma ltd  
Nexus, Gloucester Business Park  
Gloucester, GL3 4AG  
United Kingdom

##### **Manufacturer:**

Siegfried Hameln GmbH  
Langes Feld 13, 31789 Hameln, Germany  
hameln rds s.r.o.  
Horná 36, 900 01 Modra, Slovak Republic  
HBM Pharma s.r.o.  
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Zakłady Farmaceutyczne POLPHARMA S.A.  
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Poland

##### **For any information about this medicine, please contact the Marketing Authorisation Holder.**

This leaflet was last revised in 12.2023.

**Furosemide 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 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 Furosemide Injection is given to you
3. How Furosemide Injection is given to you
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 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 (listed in section 6). If you are allergic to a group of drugs called sulfonamides (e.g. Co-Trimoxazole, sulfadiazine) or sulfonamide derivatives and amiloride you may also be allergic to this injection.
- You are dehydrated, your blood volume is low (you may 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) that are affecting your consciousness.
- You previously received certain medicines that have damaged your kidneys or liver.
- 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.
- You have an illness called 'Addison's Disease'. This can make you feel tired and weak.
- You are taking digitalis preparation/digoxin/ cardiac glycosides to treat heart problems.
- You have a disease called porphyria 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 have hypotension (low blood pressure) or feel dizzy when you stand up.
- 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.
- You are an elderly patient with dementia and are also taking risperidone.
- 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.
- 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 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, methyl dopa, 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 polymyxin 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 - increased risk of furosemide toxicity.
- Ciclosporin and aldesleukin.
- 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, sertindole or phenothiazines), tricyclic antidepressants and monoamine oxidase inhibitors (medicines to treat depression) hypnotics and anxiolytics (chloral hydrate, triclofos), risperidone to treat dementia, drugs 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, terbutaline, salmeterol, formoterol or bambuterol.
- Medicines to treat blocked nose such as ephedrine and xylometazoline.
- 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. Hence it should be avoided in breast feeding women.

**Driving and using machines**

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

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

### **3. How Furosemide Injection is given to you**

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 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 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.

### **4. Possible side effects**

Like all medicines, Furosemide Injection 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.

- 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.
- Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- 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 paediatric population**

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

### **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 – website: [www.mhra.gov.uk/yellowcard](http://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 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.

Your injection will be stored at less than 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 in a sterile solution for injection.
- The other excipients are: sodium chloride, sodium hydroxide and sterile water for injections.

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Zakłady Farmaceutyczne POLPHARMA S.A.  
ul. Pelplińska 19, 83-200 Starogard Gdański, Poland

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Furosemide

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- increase the production of urine in kidney failure.

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**You should NOT be given Furosemide Injection if:**

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- You are an elderly patient with dementia and are also taking risperidone.
- 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.
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- Lithium e.g. used for mental illness.
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- Medicines to treat blocked nose such as ephedrine and xylometazoline.
- 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. Hence it should be avoided in breast feeding women.

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		<b>Leaflet Furosemide inj hameln nav UK</b>		
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Artwork No	N509432.01-UK	Dimensions	148x420 mm	Replaces SAP No. N500197.02-UK
DMcode	509432	Prepared	L.Hnilica/31.03.2025	Approved
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Furosemide Injection contains a maximum of 4 mg of sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

### 3. How Furosemide Injection is given to you

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 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 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.

### 4. Possible side effects

Like all medicines, Furosemide Injection 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.
- 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.
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- 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.
- Lichenoid reactions, characterized as small, itchy, reddish-purple, polygon-shaped lesions on the skin, genitals or in the mouth.
- 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.

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- 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

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- 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 paediatric population

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

### 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 – website: [www.mhra.gov.uk/yellowcard](http://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 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.

Your injection will be stored at less than 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 in a sterile solution for injection.
- The other excipients are: sodium chloride, sodium hydroxide and sterile water for injections.

#### What Furosemide Injection looks like and contents of the pack

Furosemide Injection is supplied in 2 ml, 5 ml and 25 ml amber glass ampoules. The injection is supplied in cartons of 10 ampoules. Not all ampoule sizes may be marketed.

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

#### Marketing Authorisation Holder:

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#### For any information about this medicine, please contact the Marketing Authorisation Holder.

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HBM Pharma		Leaflet Furosemide inj hameln nav UK					
SAP No	509432	Quality	white paper, 50 g/m <sup>2</sup>	Colours	■ Black	Replaces SAP No.	N500197.02-UK
Artwork No	N509432.01-UK	Dimensions	148x420 mm				
DMcode	509432	Prepared	L.Hnilica/31.03.2025				
		Checked	L.Kyjova/31.03.2025				
Folded leaflet size	148x210 mm / DMcodes outside						
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