Package leaflet: Information for the patient
Furosemide 250mg in 25ml Solution for Injection/Infusion
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 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.

This product will be referred to as Furosemide Injection/Infusion from here onwards.

What is in this leaflet
1. What Furosemide Injection/Infusion is and what it is used for
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1. What Furosemide Injection/Infusion is and what it is used for
Furosemide is a strong diuretic. Diuretics help you to pass more water (urine).
Furosemide Injection/Infusion may be used to help you to pass more water when your kidneys are not producing enough urine.

2. What you need to know before you are given Furosemide Injection /Infusion

You should not be given Furosemide if-
-you are allergic to furosemide or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
-you are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or cotrimoxazole
-you have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
-you have too little potassium or sodium in your blood (shown in blood test)
-you have severe liver problems (cirrhosis)
-you have already taken Furosemide in the past to treat failure to pass urine or kidney failure or if you have kidney failure that is due to medicines or chemicals that are prone to cause kidney or liver damage or if you have kidney failure due to underlying liver disorders
-you are not passing any water (urine) or 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
-you have an illness called 'Addison's Disease'. This can make you feel tired and weak
- you are taking digoxin, used to treat heart problems
-you have a disease called porphyria characterized by abdominal pain, vomiting or muscle weakness
-you are breast feeding.

Warnings and precautions

Talk to your doctor, or nurse before you are given Furosemide Injection/ Infusion.

-if you are elderly, if you are on other medications which can cause the drop the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure

-if you have low blood pressure or feel dizzy when you stand up

-if 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

-if you have low blood levels of essential minerals like sodium or potassium or you have acid base imbalance in the body identified by blood tests.

Do not take Furosemide Injection/Infusion if you are planning to undergo procedure that includes the use of radiocontrast (as taking furosemide this may increase the risk for kidney damage)

Take special precaution if-

-you are an elderly patient

-you have difficulty in passing water, for example because of an enlarged prostate gland (males only)

-you have diabetes

-you have gout (characterised by painful joints due to elevated uric acid levels)

-you have kidney or liver problems

-you have Addisons disease (inadequate functioning of the Adrenal gland)

-you have low blood protein levels 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; careful monitoring of fluids and electrolyte levels are recommended

-you have a risk of fall in blood pressure; or in case of premature infants as they may be more prone to development of kidney stones

-you are already on medicines like NSAIDs (used for inflammation and pain) or ACE inhibitors (medicines used to lower blood pressure)

-laboratory monitoring-

It is recommended to undergo regular monitoring of blood levels for sodium, potassium, kidney function tests (blood urea nitrogen and creatinine levels), glucose, magnesium, calcium, chloride, bicarbonate and uric acid

-regular monitoring is required to check for occurrence of blood dyscrasias (abnormal or imbalance in blood components), liver damage or any symptom that may occur particularly to you

-you are an elderly patient with dementia and are also taking risperidone.

Other medicines and Furosemide Injection/Infusion

Tell your doctor if you are taking, have recently taken or might take any other medicines-

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:

-Aliskiren – used to treat high blood pressure

-Tell your doctor if you are taking the below medicines as the dose of these may need to be changed to avoid the risk of excessive lowering of blood pressure. Other blood pressure lowering agents (cardiac glycosides eg digoxin, other diuretics that help you pass more urine; or other blood pressure lowering agents)

-if you are taking any drugs that can be harmful to your kidneys

-if you have low levels of potassium or magnesium in your blood indicated by the blood counts.

A large number of drugs can interact with Furosemide which can significantly alter their effects. These drugs include:

-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
-Anti-psychotics (medicines used to treat mental disorders) such as tricyclic antidepressants, hypnotics and anxiolytics (e.g pimozide, amisulpride, sertindole or phenothiazines), Risperidone used to treat dementia
-Medicines for high blood pressure or heart problems (uneven heart beat) such as calcium channel blockers, beta blockers, clonidine, moxonidine, sodium nitroprusside, amiodarone, disopyramide, flecainide, minoxidil, lidocaine, prazosin, diazoxide, methyldopa
-Cardiac glycosides (drugs used to improve heart function) eg. Digoxin which is used to treat heart failure. Your doctor may need to change the dose of your medicine
-Thymoxamine or Hydralazine used to lower blood pressure
-Metolazone- medicine used to help you pass more urine
-Nitrates- used to lower blood pressure
-Lithium- used for mental illness
-Sucralfate- this drug may decrease the absorption of Furosemide
-NSAIDs- drugs used to treat pain and inflammation (eg. Indomethacin, Ketorolac)
-Salicylates (eg aspirin)
-Antibiotics belonging to class of aminoglycosides, polymixins or vancomycin; as there may be a risk of ear or kidney damage
-Medicines used to treat depression (eg. TCA or MAOIs)
-Medicines used to treat diabetics
-Medicines used to treat epilepsy (eg Carbamazepine)
-Anti-histamines (medicines used to treat allergies)
-Anti-fungals (risk of potassium loss or renal damage indicated with Furosemide)
-Chloral or Triclorfos (drugs used to treat anxiety)
-Drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) like amphetamines
-Steroids (used to treat inflammation)
-Liquorice; increased risk of loss of potassium with Furosemide
-Platinum containing compounds like Cisplatin- used to treat cancers (increased risk of kidney damage with Furosemide)
-Methotrexate- Increase chance of Furosemide toxicity
-Levodopa- Used to treat Parkinson's disease (increased risk of lowering of blood pressure with Furosemide)
-Medicines that modify immune system- (eg Aldesleukin or ciclosporin)
-Medicines used as muscle relaxants like baclofen, tizanidine or curare like drugs
-Birth control Pills or oestrogen containing drugs may block the effect of Furosemide if taken concurrently
-Progesterone containing drugs (drosperidone) may lead to reduced blood potassium levels if taken with Furosemide
-Medicines such as alprostadil, used to treat erectile dysfunction (impotency)
-Theophylline used for wheezing or difficulty in breathing
-Probenecid used for treatment of gout
-Medicines used as general anaesthetics to induce unconsciousness
-Laxatives- drugs used to relieve constipation
-Aminoglutethimide used to treat blood cancer.

Furosemide Injection/Infusion with alcohol

- Avoid consumption of alcohol with Furosemide as it may lead to excessive lowering of blood pressure.

Pregnancy andbreast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
Furosemide passes through the placenta and hence should not be given during pregnancy unless doctor feels it extremely necessary. If it is given in cases of swelling or water retention, the growth of the baby must be regularly monitored.

Breast-feeding
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 may feel dizzy or unwell after taking Furosemide Injection/Infusion.
If this happens, do not drive or use any tools or machines.

Furosemide Injection contains sodium

This medicine contains 91mg sodium (main component of cooking/table salt) in each 25ml ampoule. This is equivalent to 4.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Furosemide Injection/Infusion is given to you

Your medicine will be given to you by a doctor or nurse. This is because it can only be given by injection. The injection may be given into a muscle (intramuscular) or slowly into a vein (intravenous).
Your doctor will decide on the most suitable dose for you, and how the medicine will be given. The dosage and frequency of repeated doses may change depending on how you respond to treatment.

Furosemide should not be administered into the vein more than 4 mg per minute.
Furosemide shall be administered into the muscle if oral and vein route are not feasible. Furosemide should not be administered through muscle more than 1500 mg per day.

The recommended dose is:
Adults: An initial dose of 250mg (one 25ml ampoule) may be added to about 225ml of the infusion fluids Sodium Chloride Injection BP or Ringer's Solution for Injection; it may then be given as a drip into a vein over one hour at a rate of 4mg per minute.
If you do not pass enough urine within the next hour, a dose of 500mg (two 25ml ampoules) may be added to a suitable infusion fluid; it may then be given as a drip into a vein at a rate not exceeding 4mg per minute.

If you still fail to pass enough urine within one hour following the end of the second dose, a dose of 1,000mg (four 25ml ampoules) may be added to a suitable infusion fluid; it may then be given as a drip into a vein at a rate not exceeding 4mg per minute. If the third dose (1,000mg over 4 hours) is not effective, your doctor may decide to filter out unwanted chemicals from the blood by a process known as dialysis.

If you are retaining too much fluid, your doctor may decide not to add the Furosemide Injection/Infusion to an infusion fluid as described above. Instead, the Furosemide Injection/Infusion may be administered into a vein through a special infusion pump at a rate not exceeding 4mg per minute.
If the response to Furosemide Injection/Infusion is satisfactory, the effective dose (of up to 1,000mg) may be repeated every 24 hours. Alternatively, your doctor may prescribe a maintenance dose of furosemide tablets, using 500mg by mouth for each 250mg required by injection.

Elderly: Furosemide can be given in elder patients in dosage same as in adults. Furosemide is generally cleared from the body more slowly in the elderly. If you are elderly, your doctor may decide to start with a low dose and increase the dose gradually according to your response.

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. The doctor will decide on the dosage, depending on how severely the kidneys are affected and on the response to initial doses.

If you think you have been given more Injection/Infusion than you should:

If you think that you have been given too much of this medicine, tell your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If any of the below mentioned side effects are observed please inform your doctor immediately

· allergic reactions such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, severe, acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin, acute generalised exanthematous pustulosis (AGEP (acute febrile drug eruption)
· sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.
· shock (severe drop in blood pressure, extreme paleness , restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances
· inflammation of the kidneys associated with blood in the urine, fever and pain in the sides (Interstitial nephritis) Rarely could also lead to acute kidney failure.
· certain liver function disorders or increase in certain liver enzymes
· a life-threatening form of unconsciousness
· Metabolic acidosis characterized by chest pain, irregular heartbeat, headache, feeling sick, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone pain and joint pain.

The other possible side effects are listed under headings of frequency, using the following categories:

Uncommon: may affect up to 1 in 100 people
· abnormal blood count accompanied by bruising and a tendency to bleed
· blurred vision

- lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright
- sensitivity to light (photosensitivity)
- feeling of tiredness
- dry mouth, thirst, disturbances of bowel like diarrhoea, constipation or vomiting
- deafness (sometimes irreversible)

Rare: smay affect up to 1 in 1,000 people

- abnormal blood count (white blood cell deficiency) accompanied by a increased susceptibility to infection
- increase in certain substances (eosinophilic cells) in the blood
- a crawling sensation on the skin, itching or tingling without any reason
- hearing disorders & ringing in the ears. These disorders are usually temporary in nature
- inflammation of a blood vessel
- fever
- muscle aches
- inability to control urination
- feeling sick or being sick, diarrhea or constipation
- if you have a urinary tract obstruction, increased urine production may occur or worsen
- if you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly
- minor mental disturbances.

Very rare: may affect up to 1 in 10,000 people

- anaemia (a condition characterised by shortage of red blood cells)
- very severe blood abnormality (white blood cell deficiency) accompanied by a sudden high fever, severe throat pain and ulcers in the mouth.
- muscle spasms due to calcium or magnesium deficiency.

Not known: frequency cannot be estimated from the available data

- Furosemide can cause an excessive depletion of bodily fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach with an urge to vomit, or diarrhoea

- if you have a shortage of sodium (sodium deficiency):
  - cramp in the calf muscles
  - loss of appetite
  - listlessness
  - feeling of weakness
  - dizziness
  - drowsiness

- if you have a shortage of potassium (potassium deficiency):
  - muscular weakness and the inability to contract one or more muscles (paralysis)
  - constipation or accumulation of gas in stomach
  - increased excretion of urine
  - heart problems

  - in the case of severe potassium deficiency: interference with the function of the intestine or confusion, which can result in coma.
- if you have a shortage of magnesium and calcium (magnesium and calcium deficiency):
  - increased irritability of the muscles
  - heart rhythm disturbances.
  - changes in glucose test
- during treatment with furosemide, the blood levels of some fats (cholesterol and triglyceride) may rise, but usually return to normal within 6 months.
- in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood.
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- in patients with diabetes use of furosemide may lead to rise in blood sugar levels which may require higher dose of insulin.
- Feeling dehydrated, tiredness, breathlessness, confusion, nausea or vomiting due to raised blood levels of creatinine and urea.
- Pain and swelling in the joints, red or purplish skin with itching and peeling around the joint which may be due to gout caused by increased levels of uric acid in blood.
- Bullous pemphigoid (an acute or chronic autoimmune skin disease, involving the formation of blisters, more appropriately known as bullae, at the space between the skin layers.)

Additional side effects in children

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

Reporting side effects
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not included in this leaflet. You can also report side effects directly via the-
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Injection/ Infusion
Do not use this medicine after the expiry date printed on the carton, after Exp.
The expiry date refers to the last day of that month.
For Single Use only.
If only part used, discard the remaining solution.
Do not store above 25°C.
Do not refrigerate or freeze.
Keep ampoules in the outer carton in order to protect from light.
Keep this medicine out of the sight and reach of children.
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/ Infusion contains

Each 25ml of sterile solution for Injection or infusion contains the active ingredient Furosemide 250 mg (10mg in 1ml).
The Other ingredients are Sodium chloride and Sodium hydroxide in water for injections.

What Furosemide Injection/Infusion looks like and contents of the pack
Furosemide Injection/Infusion is a clear, colourless or almost colourless sterile solution for infusion, presented in amber coloured glass ampoules.
Pack size: Cartons of 10 x 25ml ampoules.

Marketing Authorisation Holder
Mercury Pharmaceuticals (Ireland) Ltd
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer
Cenexi,
52, rue Marcel et Jacques,
Gaucher,
94120 Fontenay-Sous-Bois,
France

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