PATIENT INFORMATION LEAFLET

CIRIX (FUROSEMIDE INJECTION BP 10 MG/ML)
Furosemide BP

Read all of this leaflet carefully before you start taking 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.

In this leaflet:

a) WHAT CIRIX (FUROSEMIDE INJECTION BP 10 MG/ML) IS AND WHAT IT IS USED FOR

Furosemide 10 mg/ml solution for injection/infusion contains the active substance furosemide.
Furosemide belongs to a group of medicines called diuretics. It is given if sufficient urine output is not achieved by oral administration of furosemide or if oral administration is not possible.
Furosemide is used:
– to treat fluid retention in the tissue (oedema) and/or accumulation of fluid in the abdomen (ascites) due to heart or liver disease;
– to treat fluid accumulation in the tissue (oedema) due to kidney disease;
– in the case of fluid accumulation in the lungs (pulmonary oedema) (e.g. in acute heart failure);
– in case of extremely high blood pressure (hypertensive crisis) in addition to other therapeutic measures.

Do not take CIRIX (Furosemide Injection BP 10 mg/ml)

- if you are allergic (hypersensitive) to furosemide or any of the other ingredients of Furosemide Injection BP 10 mg/ml

- 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 breast-feeding;

– the patient is in a coma caused by liver failure.

Take special care with CIRIX (Furosemide Injection BP 10 mg/ml)

- you have a low blood pressure;
- you have diabetes (regular check of blood sugar is necessary)
- you have gout (painful or inflamed joints) due to high levels of uric acid (by-product of metabolism) in your blood (regular check of blood uric acid is necessary);
- you have urinary obstruction (e.g. enlarged prostate gland, swelling of a kidney due to a build-up of urine, narrowing of the ureter);
- you have abnormally low protein level in blood;
- you have liver disease
- you have rapidly progressing kidney dysfunction associated with severe liver disease (e.g. liver cirrhosis)
- you are at risk of unwanted severe blood pressure drop (e.g. if you have circulatory disorders of the cerebral vessels or the coronary arteries);
- you are dehydrated (you have lost body fluids by suffering from severe diarrhoea or being sick);
- you have the inflammatory disease called 'systemic lupus erythematosus (SLE)'
- you have hearing problems.

- Patients receiving treatment with furosemide may experience low blood pressure with dizziness, fainting or loss of consciousness. This particularly applies to the elderly, patients concomitantly taking other medicines that can cause low blood pressure and patients with other disorders associated with a risk of low blood pressure.

- Especially during long-term treatment, your doctor may regularly check your blood levels of potassium, sodium, calcium, bicarbonate, creatinine, urea, uric acid and blood sugar.
- The weight loss caused by loss of body fluid should not exceed 1 kg of body weight per day

- The use of furosemide can lead to positive results in doping controls. In addition, abuse of furosemide as a doping agent can endanger health

Taking other medicines

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- Tell your doctor or nurse, if you are using, have recently used or might use any other medicines. This is important because some medicines should not be taken together with Furosemide, or dose adjustment of furosemide or other concomitantly taken medicine may be required.
  In particular, tell your doctor or nurse if you are using:
- lithium (to treat mood disorders);
- heart medicines (e.g. digoxin);
- levothyroxine (to treat an underactive thyroid gland)
- medicines for high blood pressure including thiazide diuretics (e.g. bendroflumethiazide or hydrochlorothiazide), ACE inhibitors (e.g. lisinopril), angiotensin II antagonists (e.g. losartan)
- cholesterol or lipid-lowering medicines (e.g. colestyramine, colestipol, clofibrate);
- medicines for diabetes (e.g. metformin and insulin);
- anti-inflammatory medicines including NSAIDs (e.g. diclofenac, ibuprofen, indomethacin, celecoxib) and high doses acetylsalicylic acid (aspirin);
- corticosteroids (medicines to treat inflammation or allergy e.g. prednisolone, dexamethasone);
- carbenoxolone (to treat stomach ulcers);
- laxatives;
- chloral hydrate (to treat sleeping problems). Giving furosemide injection at the same time as chloral hydrate is not recommended since side effects such as heat, sweating, restlessness, nausea, increased blood pressure and increased heart rate may occur within 24 hours after taking chloral hydrate;
- phenytoin, phenobarbital carbamazepine (used to treat epilepsy);
- theophylline (to treat asthma);
- probenecid (used to treat gout);
- methotrexate (to treat some cancers or severe arthritis);
- ciclosporin (zto prevent rejection of transplants);
- medicines to raise your blood pressure (pressor amines such as adrenaline, noradrenaline), as they may not work as well when you receive them with furosemide;
- aminoglutethimide (used to treat Cushing's syndrome);
- sucralfate (to treat stomach ulcers). You should not receive furosemide within two hours of taking sucralfate as the effect of furosemide may be decreased;
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- cisplatin (used in cancer chemotherapy) or aminoglycoside antibiotics (e.g. kanamycin, gentamicin and tobramycin) as the side effects of these medicines on hearing may be made worse by furosemide, in particular in patients with kidney problems;
- medicines to treat heart rhythm disorders (e.g. amiodarone, sotalol, dofetilide, ibutilide);
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Taking CIRIX (Furosemide Injection BP 10 mg/ml) with food and drink

Large amounts of liquorice in combination with furosemide can lead to increased potassium losses.

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 for advice before this medicine is given to you. Furosemide should not be used during pregnancy unless there are clear medical reasons for using it. Furosemide passes into breast milk. You should not breast-feed while treated with furosemide. No data are available on fertility

Driving and using machines

Even when used as directed, this medicine may alter the ability to react to such an extent that the ability to drive, use machines or perform hazardous tasks may be impaired. This particularly applies at the start of treatment, when increasing the dose or switching medicines and in association with alcohol.

Important information about some of the ingredients of Furosemide Injection BP 10 mg/ml

b) HOW TO TAKE FUROSEMIDE INJECTION BP 10 MG/ML

Your doctor will decide how much medicine 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 using and nature and severity of your disease. The lowest dose at which the desired effect is obtained will always be used. Furosemide injection is normally given by a doctor or nurse:

– as a slow injection into a vein or
– exceptionally into a muscle.
In some cases, instead of injections, your doctor may recommend this medicine is given by continuous infusion into a vein (a drip)
You will be switched to oral administration as soon as treatment permits.

Adults
The recommended dose is 20 to 40 mg furosemide.
If your doctor thinks a higher dose is needed, you may be given further injections at appropriate intervals until the desired fluid loss occurs. The In adults, the maximum daily dose of furosemide should not exceed 1500 mg.

Patients with renal impairment
In patients with severe renal impairment (serum creatinine > 442 micromol/l [>5 mg/dl]) it is recommended that an infusion rate of 2.5 mg furosemide per minute is not exceeded.

Elderly
The usual initial dose in elderly is 20 mg daily. This can be gradually increased until the desired fluid loss is achieved.

Use in children and adolescents over 15 years
Infants and children under 15 years should be given furosemide by injection/infusion only as an exception in threatening situations. The mean daily dose is 0.5 mg furosemide/kg body weight. Exceptionally, up to 1 mg furosemide/kg body weight can be injected into a vein.

If you take more Furosemide Injection BP 10 mg/ml than you should

If you think you have been given too much of this medicine, tell your doctor straight away. The signs of acute or chronic overdose depend on the extent of salt and fluid loss. Symptoms of overdose are dry 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 have any further questions on the use of this medicine, ask your doctor or nurse.

If you forget to take use Furosemide Injection BP 10 mg/ml

If you forget your dose, take it as soon as you remember. But, if it is nearly time for your next dose, just take the next dose at the right time. Do not take double the dose.

If you stop taking Furosemide Injection BP 10 mg/ml

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

c) POSSIBLE SIDE EFFECTS

Very common (may affect more than 1 in 10 patients)
- Electrolyte disturbances (including symptomatic), dehydration and decreased circulating blood flow volume (especially in elderly), increased levels of certain blood lipids (triglycerides)
- Low blood pressure including circulatory disturbances when changing from lying to upright position (with infusion into a vein)
- Increased blood creatinine (indicates how your kidneys are working)

Common (may affect up to 1 in 10 patients)
- Blood thickening (in case of excessive urine excretion)
- Reduced sodium and chloride level in blood (especially with restricted sodium chloride intake), low potassium level in blood (especially with concomitant reduction of potassium intake and/or increased potassium losses, e.g. due to vomiting or chronic diarrhoea), blood cholesterol increased, blood uric acid increased and gout flare
- Brain function disorders as a result of severe liver impairment (hepatic encephalopathy)
- Urine volume increased

Uncommon (may affect up to 1 in 100 patients)
- Low blood platelet count (thrombocytopenia)
- Increased blood sugar. This can lead to a worsening of the metabolic status in patients with existing diabetes (manifest diabetes). An unrecognized diabetes (latent diabetes) may become manifest

- Hearing disorders, mostly reversible, especially in patients with kidney impairment or decreased protein level in blood (e.g. in cases of nephrotic syndrome) and/or if the medicine is injected too fast into the vein
- Deafness (sometimes irreversible)
- Feeling sick
- Itching, hives, rash, skin and mucous membrane reactions with redness, blistering or flaking (e.g. bullous dermatitis, erythema multiforme, pemphigoid, exfoliative dermatitis, purpura), increased sensitivity of skin to sunlight

Rare (may affect up to 1 in 1,000 patients)
- Increased number of a certain type of white blood cells (eosinophilia)
- Reduced number of white blood cells (leukopenia)
- Tingling, numbness or painful burning sensation in the limbs
- Ringing in the ears (tinnitus)
- Inflammation of the blood vessels (vasculitis)
- Vomiting, diarrhoea
- Kidney damage (interstitial nephritis)
- Fever

Very rare (may affect up to 1 in 10,000 patients)
- Anaemia due to abnormal breakdown of red blood cells (haemolytic anaemia)
- Condition in which the bone marrow stops to produce enough new blood cells (aplastic anaemia)
- Severe reduction of certain type of white blood cells (agranulocytosis). Signs may include fever with chills, mucosal changes and sore throat
- Acute inflammation of the pancreas
- Liver disorder called 'intrahepatic cholestasis' and increased levels of liver enzymes in the blood which may cause jaundice (yellow skin, dark urine, tiredness)

Not known (the frequency cannot be estimated from the available data)
- Systemic lupus erythematosus (SLE) may get worse or be activated
- Low calcium level in blood, low magnesium level in blood, decreased blood pH (metabolic acidosis), pseudo-Bartter syndrome (renal impairment related to misuse and/or long-term use of furosemide)

Commonly observed symptoms of low sodium level in blood are apathy, calf cramps, loss of appetite, weakness, drowsiness, vomiting and confusion.
Low potassium level in blood can manifest as muscle weakness, abnormal sensations in limbs (tingling, numbness or painful burning sensation), inability to move a body part (paresis), gastrointestinal symptoms (vomiting, constipation, excessive gas accumulation in the gastrointestinal tract), kidney symptoms (excessive urinary excretion, abnormally increased thirst) and cardiac symptoms (or slow or irregular heart rhythm). Severe potassium losses can lead to intestinal paralysis (paralytic ileus) or impaired consciousness and even coma.
Low calcium level in blood can induce tetany in rare cases.
As a result of low magnesium level in blood, tetany or occurrence of heart rhythm disorders has been observed in rare cases.
- Dizziness, fainting and loss of consciousness, headache

- Occlusion of a blood vessel by blood clots (thrombosis, especially in elderly patients) Excessive urinary excretion, especially in elderly patients and children, circulatory problems (up to circulatory collapse) may occur, mainly manifested as headache, dizziness, blurred vision, dry mouth and thirst, low blood pressure and circulatory disorders when changing from lying to upright position
- Severe skin reactions (may affect also mucosa)

  e.g. blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis (AGEP), drug eruption with eosinophilia and systemic symptoms and lichenoid reactions, which manifest as small, itchy, reddish-purple lesions on the skin, genitals, or in the mouth)
- Muscle problems (rhabdomyolysis) often in association with severe potassium deficiency
- Urine sodium increased, urine chloride increased, blood urea increased, symptoms of urinary obstruction (e.g. in patients with enlarged prostate gland, swelling of a kidney due to a build-up of urine, narrowing of the ureter) and even urinary retention; deposition
  of calcium in the kidney and/or kidney stones in preterm infants, kidney failure
- Increased risk of patent ductus arteriosus when preterm infants are treated with furosemide in the first weeks of life
- Pain after injection into a muscle

d) HOW TO STORE MORE FUROSEMIDE INJECTION BP 10 MG/ML

This medicine does not require any special temperature storage conditions.
Keep the ampoules in the outer carton in order to protect from light. Do not refrigerate or freeze.

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 label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

e) FURTHER INFORMATION

What more Furosemide Injection BP 10 mg/ml contains

- The active substance is Furosemide BP
- The other ingredient is Sodium Hydroxide, Sodium Chloride, Water For Injection

What Furosemide Injection BP 10 mg/ml looks like and contents of the pack

- A Colorless or Almost Colorless Solution.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C-1101 / 1102, Lotus Corporate Park, Graham Firth Steel Compound,
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For any information about this medicinal product, please contact the <local representative of the> supplier:

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