

Lasix®

Furosemide BP



Presentation

Lasix tablet : Nearly white, round biplaner tablets with break line. Each tablet contains Furosemide BP 40mg as active ingredient.

Lasix injection : Amber coloured ampoule containing Furosemide Sodium BP 21.3mg (equivalent to Furosemide BP 20mg) in 2ml clear colourless solution.

Indications

Tablet : Oedema due to cardiac, hepatic or renal disorders (in the presence of nephrotic syndrome, treatment of the basic disorder is the prime concern). Oedema due to burns. Mild to moderate hypertension.

Injection : Oedema due to cardiac and hepatic disease (ascites). Oedema due to renal disease (in the nephrotic syndrome therapy of the underlying diseases has precedence). Acute cardiac insufficiency especially in pulmonary oedema (administration in conjunction with other therapeutic measures). Reduced urinary output due to gestoses (after restoring the fluid volume to normal). Supportive measures in brain oedema. Oedema due to burns. Hypertensive crisis (in addition to other antihypertensive measures). To support forced diuresis in poisoning.

Dosage

Tablet : Unless otherwise prescribed, the following dosage guidelines apply: In adults, treatment usually begins with 1/2-1-2 tablets daily; the maintenance dose is 1/2-1 tablet daily. In infant and children, Lasix should in principle be administered orally. The dosage recommendation is 2mg furosemide per kg body weight up to a daily maximum of 40mg. Parenteral administration (if necessary, continuous drip infusion) is indicated only in life-threatening conditions.

Injection : Unless otherwise prescribed, the initial dose for adults and adolescents of 15 years or over is 20 to 40mg Lasix (1-2 ampoules) intravenously or intramuscularly.

If after a single dose of 20 to 40mg Lasix (1-2 ampoules) the diuretic effect is not satisfactory, the dose may be stepwise increased, at two-hourly intervals, by 20mg (1 ampoule) each time, until satisfactory diuresis is obtained. The individual dose thus established should then be given once or twice daily.

Actue pulmonary oedema : An intial dose of 40mg Lasix (2 ampoules) is administered intravenously. If the patient's condition requires it, a further dose of 20-40mg Lasix (1-2 ampoules) is injected after 20 minutes.

Forced diuresis : 20-40mg Lasix (1-2 ampoules) is given in addition to infusion of electrolyte solution.

Further treatment depends on the elimination of urine and must include substitution of the fluid and electrolyte losses.

In poisoning with acid or basic substances, the elimination rate can be further increased by alkalinisation or acidification, respectively, of the urine.

Infants and children under 15 years : In principle, Lasix should be administered orally. Parenteral administration (if necessary, continuous drip infusion) is indicated only in life threatening conditions.

For intravenous or intramuscular injection, the dosage schedule is 1mg furosemide per kg body weight up to a daily maximum of 20mg Lasix (1 ampoule). Therapy should be changed to oral administration as soon as possible.

Administration

Tablet : The tablets should be swallowed whole with a little fluid on an empty stomach. The duration of treatment is determined by the doctor and will depend on the nature and severity of illness.

During long-term therapy, serum creatinine and urea, as well as plasma electrolytes, in particular potassium, calcium, chloride, and bicarbonate, should be regularly checked.

Patients must be regularly monitored by the doctor, if Lasix is used to treat high blood pressure.

Injection : Intravenous or intramuscular administration of Lasix 20mg is indicated in all cases where intestinal absorption is impaired or rapid fluid elimination is necessary.

Intravenously, Lasix 20mg should be injected slowly. The rate of injection of 4mg per minute should not be exceeded.

During long-term therapy, serum creatinine and urea, as well as plasma electrolytes, in particular potassium, calcium, chloride, and bicarbonate, should be regularly checked.

Furosemide, being an anthranilic acid derivative, dissolves in alkaline media with salt formation. The solution for parenteral application contains the sodium salt of the carboxylic acid without a solubilizer. The solution has a pH of about 9 but no buffer capacity, which means that the drug may precipitate at pH values below 7. If the ready-to-use solution has a pH ranging from weakly alkaline to neutral, the mixtures may be used for up to 24 hours.

Lasix 20mg must not be mixed with other drugs in the same injection syringe.

The duration of treatment is determined by the doctor and will depend on the nature and severity of illness.

Contraindications

Renal failure with lack of urine formation (anuria), hepatic coma and precoma, severe hypokalaemia, severe hyponatraemia, hypovolaemia with or without hypotension, hypersensitivity to furosemide or sulphonamides.

Precautions

Particularly careful surveillance is necessary in :

- markedly reduced blood pressure
- latent or manifest diabetes mellitus (regular blood sugar checks)
- gout (regular uric acid checks)
- obstructed micturition (e.g. in prostatic hypertrophy, ureterostenosis, hydronephrosis)
- concurrent presence of hepatic cirrhosis and impairment of renal function
- hypoproteinaemia (e.g. in the nephrotic syndrome)
- premature infants possible development of kidney stones containing calcium [nephrolithiasis] and of calcium salt deposition in the renal tissue [nephrocalcinosis]; renal function must be monitored and renal ultrasonography performed.

If furosemide is used in patients with mild hypokalaemia or hyponatraemia, appropriate electrolyte substitution must be implemented at the same time.

Furosemide should be administered during pregnancy only if strictly indicated, and then only for short periods of time.

In breast-feeding mothers where the use of furosemide is considered necessary, it should be borne in mind that furosemide passes into the breast milk and inhibits lactation. It is advisable to stop nursing in such cases.

Drug interactions

Hypokalaemia or hypomagnesaemia may possibly develop and increase the sensitivity of the myocardium to cardiac glycosides (digitalis products).

Increased potassium loss may occur in the event of concomitant medication with glucocorticoids, laxatives, or carbenoxolone. In this respect, liquorice acts in the same way as carbenoxolone.

The ototoxic effects of aminoglycosides (e.g. kanamycin, gentamicin, tobramycin) may be potentiated by concomitant administration of furosemide. Since the resultant disorders of hearing may be irreversible, concurrent use should be restricted to vital indications.

There is a possibility of hearing impairment if cisplatin and furosemide are used concurrently. If the aim is to increase urine excretion with furosemide (forced diuresis) during cisplatin treatment, care must be taken that furosemide is used only in low doses (e.g. 40mg where kidney function is normal) and with positive fluid balance, otherwise, the nephrotoxicity of cisplatin may be enhanced.

Furosemide may potentiate the harmful effects on the kidney of nephrotoxic antibiotics (e.g. aminoglycosides, polymyxins).

Concurrent administration of non-steroidal anti-inflammatory drugs (e.g. indomethacin, acetylsalicylic acid) may cause acute renal failure in patients with a pre-existing reduction in circulating blood volume (hypovolaemia).

Non-steroidal anti-inflammatory drugs (e.g. indomethacin, acetylsalicylic acid) and probenecid may attenuate the effect of furosemide. Attenuation of the effect of furosemide has also been

described following concurrent administration of phenytoin.

The action of other antihypertensive agents may be potentiated by furosemide. Especially in combination with ACE inhibitors, a marked fall in blood pressure and even shock has been observed.

The administration of ACE inhibitors to patients pre-treated with furosemide may lead to a deterioration in renal function and, in isolated cases to acute renal failure. The effect of antidiabetics or of pressor amines (e.g. adrenaline, noradrenaline) may be attenuated, and the effect of theophylline or curare - type muscle relaxants may be potentiated.

Due to the action of furosemide, the excretion of lithium is reduced thus enhancing the cardiotoxic and neurotoxic effect of lithium.

The toxicity of high-dose salicylates may be potentiated if furosemide is administered concurrently.

Sensation of heat, sweating, restlessness, nausea, raised blood pressure, and tachycardia may be encountered in isolated cases following intravenous administration of furosemide within 24 hours after the ingestion of chloral hydrate.

Concurrent administration of furosemide and sucralfate should be avoided, as sucralfate reduces the absorption of furosemide and, hence, weakens its effect.

Adverse reactions

Disturbances of water and electrolyte balance are frequently observed as a result of increased electrolyte excretion.

Excessive diuresis may give rise, especially in elderly patients and children, to circulatory disturbances which manifest themselves particularly as headache, dizziness, visual impairment, dryness of the mouth, hypotension, and disturbed circulatory regulation on assuming an erect posture. In addition, it may give rise to a loss of body water (dehydration) and, as a consequence of the reduced circulating blood volume (hypovolaemia), to an increase in the concentration of the blood (haemoconcentration) with-in elderly patients in particular-thrombophilia.

Sodium deficiency (hyponatraemia) may occur as a result of increased sodium losses via the kidney- especially where salt intake is restricted. This often manifests itself in the following symptoms: calf cramps, loss of appetite, a feeling of weakness, drowsiness, apathy, confusion, vomiting.

A postassium deficiency state (hypokalaemia) may occur as a result of increased extra-renal potassium losses, particularly when potassium intake is simultaneously diminished and / or extra-renal potassium losses are increased (e.g. due to vomiting or chronic diarrhoea). In addition, patients with diseases such as cirrhosis of the liver have a tendency to develop potassium deficiency states. Appropriate surveillance and, where necessary, replacement therapy are required in such cases.

Potassium deficiency may manifest itself in neuromuscular symptoms, e.g. muscular weakness and incomplete or complete paralysis, in intestinal symptoms, e.g. vomiting, constipation, and excessive gas accumulation in the abdomen or intestine (meteorism), in renal symptoms, e.g. the passage of excessive volumes of urine (polyuria), increased thirst and excessive drinking (polydipsia), and in cardiac symptoms (disturbances of impulse formation and conduction). Severe potassium losses may lead to intestinal paralysis (paralyticileus) or to disorders of consciousness, sometimes progressing to coma.

Increased renal calcium losses may lead to a calcium deficiency state (hypocalcaemia). This may trigger a state of increased neuromuscular irritability, accompanied by tetany in rare cases. In premature infants, kidney stones containing calcium (nephrolithiasis) may develop and calcium salts may be deposited in the renal tissue (nephrocalcinosis).

A magnesium deficiency state (hypomagnesaemia) and, in rare, cases, tetany or cardiac arrhythmias have been observed as a consequence of increased renal magnesium losses.

Symptoms of existing obstructed micturition (e.g. in prostatic hypertrophy, ureterostenosis, hydronephrosis) may be triggered or aggravated by pronounced diuresis.

Levels of serum lipids (cholesterol and triglyceride) may rise during furosemide treatment. Serum levels of creatinine and urea may rise transiently. The concentration of uric acid in the blood is frequently increased during medication with furosemide. This may lead to gout attacks in predisposed patients. Glucose tolerance may be reduced during furosemide treatment. In diabetic patients, this may lead to a deterioration of metabolic condition, latent diabetes mellitus may become manifested. Isolated cases of acute pancreatitis have been observed.

Disorders of hearing, in most cases reversible, and / or noises in the ears (tinnitus) may occur in rare cases. They are likely to occur mainly when furosemide is administered too rapidly by in intravenous injection, especially in patients with renal insufficiency (See " Administration").

Pre-existing metabolic alkalosis (e.g. in decompensated cirrhosis of the liver) may be aggravated. Gastrointestinal disorders such as nausea, vomiting, or diarrhoea occur in rare cases.

Allergic reactions may be seen occasionally. A violent and sometimes acutely life-threatening reaction (anaphylactic and anaphylactoid reactions) with e.g. circulatory collapse (shock) is rare and has previously only been described following intravenous administration (for recommended measures, see below). As a general rule, allergic reactions may take the form of cutaneous reactions (e.g. itching, urticaria bullous eruptions, erythema multiforme, exfoliative dermatitis, purpura) but also of febrile states, inflammation of the blood vessels or kidneys (vasculitis or interstitial nephritis).

Furosemide may cause changes in blood picture: there have been rare reports of eosinophilia, of haemolytic or aplastic anaemia, of a decrease in the number of leucocytes or of agranulocytosis associated in certain cases with increased proneness to infections, and occasional reports of a decrease in the number of platelets (thrombocytopenia) associated in certain instances with an increased bleeding tendency. These changes in blood picture may be life-threatening.

Disturbances of sensation (paraesthesiae) occur in rare cases, and photosensitivity of the skin has been noted occasionally.

In premature infants with respiratory distress syndrome, furosemide administered during the first weeks of life may increase the risk of persistence of Botallo's duct.

The ability to drive, cross the road safely, or operate machinery may be impaired both as a result of a reduction in blood pressure and of other adverse reactions cited above. This applies especially at the commencement of treatment, when changing over from other drugs or when alcohol is consumed during furosemide therapy.

Special notes

Although administration of Lasix 20mg only rarely leads to hypokalaemia, a potassium-rich diet (lean meat, potatoes, bananas, tomatoes, cauliflower, spinach, dried fruit, etc.) is always advisable. Occasionally, treatment with potassium-containing or potassium-sparing preparations may be indicated.

Emergency measures to be taken in the event of anaphylactic shock

Generally, the following emergency procedure is recommended : At the first signs (sweating, nausea, cyanosis), interrupt the injection immediately, but leave the venous cannula in place or perform venous cannulation. In addition to the usual emergency measures, ensure that the patient remains lying, with the legs raised and airways patent.

Emergency drug therapy

Immediately epinephrine (adrenaline) i.v. : Dilute 1 ml of commercially available epinephrine solution 1: 1000 to 10 ml. In the first instance, slowly inject 1 ml of this dilution (equivalent to 0.1 mg epinephrine) while monitoring pulse and blood pressure (watch for disturbances of cardiac rhythm). Repeat as required.

Then glucocorticoids i.v. e.g. 250-1000mg methylprednisolone. Repeat as required.

The dosage recommendations refer to adults of normal weight. In children, the reduction of dose should be in relation to body weight.

Subsequently volume substitution i.v. e.g. plasma expanders, human albumin, balanced electrolyte solution.

Other therapeutic measures, e.g. artificial respiration, oxygen inhalation. antihistaminics.

Storage

Protect from light.

Package quantities

Lasix tablet : Box of 10 x 10 x 40mg in blister packs

Lasix injection : Box of 25 x 2ml ampoules

Do not use later than the date of expiry

Keep all medicines out of the reach of children

To be dispensed only on the prescription of a registered physician

Manufactured by:


 **synovia**

Synovia Pharma PLC., Station Road, Tongi, Gazipur.

Under License From **Sanofi, France.**

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Direction Slip artwork legend

Product Name	:	Lasix
Code number	:	584826/2
CCDS Version	:	02
Dimension	:	L 12.15 x W 3.74 inches
Min. size of text	:	8 pt
Used Colors	:	Black C  Red 