For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Abridged Prescribing Information

LASIX®
Frusemide Tablets I.P.
Frusemide Injection I.P.

COMPOSITION: Lasix Tablets: Each uncoated tablet contains 40 mg Frusemide
Lasix 2ml (20mg) and 4ml (40mg) Injection: Each 1ml ampoule contains 10mg Frusemide.

THERAPEUTIC INDICATIONS : Indicated in fluid retention associated with chronic congestive cardiac failure (if diuretic treatment is required), fluid retention associated with acute congestive cardiac failure, fluid retention associated with chronic renal failure, maintenance of fluid excretion in acute renal failure, including that due to pregnancy or burns, fluid retention associated with nephrotic syndrome (if diuretic treatment is required), fluid retention associated with liver disease (if necessary to supplement treatment with aldosterone antagonists), hypertension, hypertensive crisis (as a supportive measure), support of forced diuresis.
DOSAGE AND ADMINISTRATION: **Adults**: Depending upon the indication the usual initial dose ranges from 20mg to 80mg. The recommended maximum daily dose for both oral and intravenous is 1500mg. **Children:** 2mg/kg body weight up to a maximum daily dose of 40 mg for oral administration. In case of parenteral administration dose is 1 mg/kg body weight up to a maximum daily dose of 20 mg. Duration depends on the indication and is determined on an individual basis.
SAFETY-RELATED INFORMATION
Contraindications : Lasix must not be used in case of hypersensitivity to frusemide or any of the excipients; patients allergic to sulfonamides (e.g. sulfonamide antibiotics or sulfonyl ureas) may show cross-sensitivity; in patients with hypovolaemia or dehydration, anuric renal failure not responding to frusemide, severe hypokalaemia, severe hyponatraemia; pre-comatose and comatose states associated with hepatic encephalopathy; in breast-feeding women.
Precautions: Urinary outflow must be secured. Patients with partial obstruction of urinary outflow require careful monitoring. Treatment with Lasix requires regular medical supervision. Careful monitoring is necessary particularly in patients with hypotension, in patients who would be at risk from a pronounced fall in blood pressure, e.g. patients with stenoses of coronary arteries or of the blood vessels supplying the brain; in patients with latent or manifest diabetes mellitus, gout, hepatorenal syndrome, hypoproteinaemia; in premature infants. Regular monitoring of serum sodium, potassium and creatinine recommended. Hypovolemia or dehydration as well as any significant electrolyte / acid-base disturbance must be corrected. Caution should be exercised and the risks and benefits of combination with risperidone or co-treatment with other potent diuretics should be considered prior to the decision to use. The possibility exists of exacerbation or activation of systemic lupus erythematosus. Aliskiren reduces plasma concentration of furosemide given orally. In patients treated with both aliskiren and oral furosemide, it is recommended to monitor for reduced diuretic effect and adjust the dose accordingly.
Pregnancy: Frusemide crosses the placental barrier, hence it must not be given during pregnancy unless there are compelling medical reasons. Treatment during pregnancy requires monitoring of fetal growth.
Lactation: Passes into breast milk and may inhibit lactation; women treated must not breast feed.
Adverse Reactions : Very common and common adverse reactions include electrolyte disturbances (including symptomatic) , dehydration and hypovolaemia especially in elderly patients, blood creatinine increase, blood triglyceride increase, hyponatremia, hypochloremia, hypokalemia, blood cholesterol increase, blood uric acid increase and attacks of gout, hypotension including orthostatic hypotension, urine volume increase, hepatic encephalopathy in patients with hepatocellular insufficiency, haemoconcentration.
For full prescribing information please contact: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072.
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