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

Frusemide & Spironolactone Tablets
LASILACTONE 50

Abridged Prescribing Information

COMPOSITION: Each tablet contains: 20mg Frusemide and 50 mg Spironolactone.
THERAPEUTIC INDICATIONS: Lasilactone is indicated for the treatment of resistant oedema where this is associated with secondary hyperaldosteronism; conditions include congestive cardiac failure and hepatic cirrhosis. Treatment with Lasilactone should be reserved for cases refractory to a diuretic alone at conventional doses.
DOSAGE AND ADMINISTRATION: 1-4 tablets daily. Not suitable for children. An evening dose is not recommended because of increased nocturnal urine output.

SAFETY RELATED INFORMATION
CONTRAINDICATIONS: Lasilactone® must not be used: in patients with hypovolaemia or dehydration, in patients with impaired renal function and a creatinine clearance below 30 ml/min per 1.73 m2 body surface area, acute renal failure, or anuria, in patients with hyperkalaemia, in patients with severe hypokalaemia, in patients with severe hyponatraemia, in patients with pre-comatose and comatose states associated with hepatic encephalopathy, in lactating women, during pregnancy (for spironolactone component), in patients with hypersensitivity to frusemide, spironolactone or any of the excipients of Lasilactone.
For Frusemide: Lasilactone® must not be used: Patients allergic to sulfonamides (e.g. sulfonamide antibiotics or sulfonylureas) may show cross-sensitivity to frusemide.

WARNINGS AND PRECAUTIONS: Related to Lasilactone : Its use in children is not recommended. Urinary outflow must be secured. In patients with a partial obstruction of urinary outflow increased production of urine may provoke or aggravate complaints. Thus, these patients require careful monitoring - especially during the initial stages of treatment. Treatment with Lasilactone necessitates regular medical supervision. Particularly careful monitoring is necessary in patients with hypotension. Treatment with lasilactone requires regular monitoring of serum sodium, potassium, and creatinine. Frequent checks of the serum potassium level are necessary in patients with impaired renal function and a creatinine clearance below 60 ml/min per 1.73 m2 body surface area as well as in cases where Lasilactone is taken in combination with certain other drugs which may lead to an increase in potassium concentration. Particularly close monitoring is required in patients at high risk of developing electrolyte imbalances or in case of significant additional fluid loss. Hypovolaemia or dehydration as well as any significant electrolyte and acid-base disturbances must be corrected, may require temporary discontinuation. **Related to Frusemide** : Possibility of exacerbation or activation of systemic lupus erythematosus. Concomitant use: Risperidone :Caution should be exercised and the risks and benefits of this combination or co-treatment with other potent diuretics should be considered prior to the decision to use. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be avoided in elderly patients with dementia. Careful monitoring is necessary: In patients who would be at particular risk from a pronounced fall in blood pressure, patients with latent or manifest diabetes mellitus, gout, with hepatorenal syndrome, hypoproteinaemia. Cautious dose titration is required. In premature infants renal function must be monitored and renal ultrasonography performed. **Related to Spironolactone:** For some patients with metastatic castration-resistant prostate cancer, tumor progression has been observed during spironolactone treatment. Spironolactone may cause vocal changes. Particularly careful monitoring is necessary in patients with reduced renal function.
PREGNANCY & LACTATION: Not to be given in pregnancy. Use of Lasilactone is contraindicated during lactation
ADVERSE REACTIONS : Very common and common adverse reactions :
Lasilactone: Hyponatremia (common)
Related to frusemide : Electrolyte disturbances (including symptomatic), dehydration and hypovolaemia especially in elderly patients (very common)

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.
Date: June 2021
References:

1. Spironolactone+Frusemide CCSI Version 01 dated 23Aug 2018
2. Lasilactone Capsule UK SPC dated May 2021 (Accessed on 12th June 2021)