Summary Of Product Characteristics

1. Name of the medicinal product.

Lefrusid tablets.

2. Qualitative and quantitative composition.

Each tablet contains: Furosemide BP 40mg and excipients listed in section 6. 1.

3. Pharmaceutical form.

Tablets.

White to off white, circular, FFBE tablet scored on one side and plain on reverse. Packed in blisters of 10x10's and contained in unit box and in 1000's in HDPE container with literature insert.

4. Clinical particulars.

4.1 therapeutic indications.

Lefrusid is indicated for the management of the following: -

1. Oedema associated with congestive heart failure, cirrhosis of the liver, renal disease and nephrotic syndrome. In all these cases, furosemide tablet is the first choice of treatment.
2. Lefrusid tablet is indicated in hypertension often in combination with other antihypertensives.
3. Renal insufficiency.

4.2 posology and method of administration

Adults:

Oedema

20 to 80mg in single dose or depending on response to be repeated after 6 to 8 hours in increments of 20 to 40mg once or twice daily.

Hypertension

40 to 80mg daily by mouth either alone or in conjunction with other anti-hypertensives.

Renal insufficiency:

Initial 250mg may be given by mouth increased, if necessary, in steps of 250mg every 4 to 6 hours to a maximum of 1.5g in 24hours.

Children: usual doses: 1 to 3mg/kg body weight up to a maximum of 40mg daily.

4.3 Contraindications

Furosemide is contra-indicated in: -

1. Patients who are hypersensitive to furosemide.
2. Anuria or in renal failure due to nephrotoxic or hepatotoxic drugs.
3. Renal failure associated with hepatic coma.
4. Pre-comatose states associated with hepatic cirrhosis.

4.4 Special warnings and precautions for use.

1. Use with caution in patients with severe renal and hepatic insufficiency.
2. Furosemide may increase the toxicity of digitalis in cardiac failure patients (see interactions)

4.5 Interaction with other medicinal products and other forms of interaction.

Furosemide is known to interact with a number of drugs. It increases the toxicity of lithium, digitalis and theophylline. It decreases arterial responsiveness of adrenaline. It antagonises skeletal muscle relaxant effects of tubocurarine.

4.6 Pregnancy and lactation.

Furosemide crosses placental barrier and hence its use should be carefully monitored during pregnancy especially first trimester. Patients are advised to consult their doctor.

4.7 effects on ability to drive and use machines.

None known.

4.8 Undesirable effects.
Fluid and electrolyte imbalance including hyponatraemia, hypokalemia due to large doses or prolonged administration, ototoxicity which is dependent on plasma concentration. Other side effects include allergy, nausea diarrhoea, blurred vision, yellow vision, dizziness, headache, skin rashes, photosensitivity and pancreatitis. Furosemide may also provoke hyperglycaemia and glycosuria. It may also precipitate hyperuricaemia worsening gout.

4.9 Overdose.
The principal signs and symptoms of overdose with furosemide are dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia and hypochloremic alkalosis, and are extensions of its diuretic action. The acute toxicity of furosemide has been determined in mice, rats and dogs. In all three, the oral ld50 exceeded 1000 mg/kg body weight, while the intravenous ld50 ranged from 300 to 680 mg/kg. The acute intragastric toxicity in neonatal rats is 7 to 10 times that of adult rats. The concentration of furosemide in biological fluids associated with toxicity or death is not known. Treatment of overdosage is supportive and consists of replacement of excessive fluid and electrolyte losses. Serum electrolytes, carbon dioxide level and blood pressure should be determined frequently. Adequate drainage must be assured in patients with urinary bladder outlet obstruction (such as prostatic hypertrophy). Hemodialysis does not accelerate furosemide elimination**.**

5. Pharmacological properties
5.1 pharmacodynamic properties.
Pharmacotherapeutic group: **Cardiovascular apparatus. Antihypertensives. Diuretics, Diuretics of loop.**
ATC code: **C03CA01**
Lefrusid contains furosemide, a 4-chloro-n-furfuryl-5-sulphamoyl anthranilic acid which is a potent, rapid action diuretic. It acts by inhibiting the reabsorption of sodium and chloride ions at the ascending limb of the loop of henle. Other minor sites of action include proximal and distal tubules. The action at distal tubule is independent of any inhibitory effect on carbonic anhydrase and aldosterone

5.2 pharmacokinetic properties.
Furosemide is fairly rapidly absorbed from gastrointestinal tract. Bioavailability is about 60% to 70% but absorption, is variable and erratic. The half-life of furosemide is up to 2 hours but is prolonged in neonates, elderly, patients with renal and hepatic insufficiency.
Furosemide is highly albumin bound up to 99%. It is mainly excreted via urine, largely unchanged, small amount is excreted via bile.
Furosemide crosses the placental barrier and it should be used with caution especially the first trimester.
It is also excreted through breast milk.

5.3 preclinical safety data.
Not applicable

6. Pharmaceutical particulars
6.1 list of excipients.
- Lactose monohydrate.
- White corn starch.
- Sodium starch glycolate.
- Sodium lauryl sulphate.
- Povidone K-90.
- Potassium Sorbate.
- Sodium Benzoate.
- Purified water.
- Magnesium stearate.
- Aerosil 200.
- Sodium starch glycolate.

6.2 incompatibilities.
None known

6.3 shelf life.
36 Months.
6.4 special precautions for storage.
Store in a dry place below 30°C.
Protect from light.
Keep all medicines out of reach of children.

6.5 nature and contents of container.
Packed in blisters of 10x10's and contained in a unit box and in 1000's in HDPE container with literature insert.

6.6 special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses.
Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,
Country : Kenya
Telephone : +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com.

Manufacturing Site Address:
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Country : Kenya
Telephone : +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com

8. Marketing Authorization Number:
Kenya: H95/419

9. Date of first Registration/ Renewal of the Registration:
Date of registration: 30/07/1995
Retained: Annually.

10. Date of revision of the text:
March 2024.

11. Dosimetry (if applicable)
Not Applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)
Not Applicable.