

# Edenil<sup>®</sup>

Furosemide & spironolactone tablet

## DESCRIPTION

**Edenil<sup>®</sup>** contains two active ingredients: furosemide, a short acting loop-diuretic and spironolactone, a long acting aldosterone antagonist. This combination produces a strong synergistic or additive diuretic effect. Furosemide inhibits Na<sup>+</sup>/K<sup>+</sup>/2Cl<sup>-</sup> co-transport in the ascending loop of Henle and there occur inhibition of sodium, potassium and chloride ions and water re-absorption. Spironolactone acts on collecting tubules to block the aldosterone receptors and inhibits the re-absorption of sodium and excretion of potassium at the distal tubule. So that sodium excretion is greatly favored and the excess loss of potassium induced by furosemide is reduced.

## INDICATIONS

**Edenil<sup>®</sup>** is indicated for the treatment of

- Oedema (swelling due to excess fluid retention)
- Congestive heart failure
- Liver cirrhosis, with ascites (collection of fluid in the abdominal cavity)
- Essential hypertension
- Hyperaldosteronism (overproduction of aldosterone)

## DOSAGE AND ADMINISTRATION

1-4 tablets (20-80 mg of furosemide and 50-200 mg of spironolactone) daily according to the patient's response. **Edenil<sup>®</sup>** is not suitable for use in children.

## CONTRAINDICATIONS

Furosemide & spironolactone combination is contraindicated in patients with acute renal failure, renal insufficiency (creatinine clearance: <30ml/min), anuria, hyperkalemia, hyponatremia, Addison's disease or in patients with known hypersensitivity to any of the components of this product.

## USE IN PREGNANCY & LACTATION

**Edenil<sup>®</sup>** should be used with caution during pregnancy, only when expected benefit to the mother is greater than the possible risk to the fetus.

**Edenil<sup>®</sup>** passes into breast milk. It is recommended that mothers should avoid using this medicine while breastfeeding.

## SIDE-EFFECTS

Generally **Edenil<sup>®</sup>** is well tolerated. However a few side effects like fatigue,

skin rashes, diarrhea, constipation, nausea, vomiting, abdominal pain, hyperglycemia, hypotension, gynecomastia, irregular menstrual cycle and impotence may occur.

## PRECAUTION

Caution should be taken in patients liable to electrolyte insufficiency. This combination drug should also be used with caution in diabetes, enlarged prostate, hypotension and in hypovolemia.

## DRUG INTERACTIONS

- When taken together with ACE inhibitors or potassium salts there is an increased risk of hyperkalemia.
- Spironolactone increases the levels of cardiac glycosides such as digoxin in the blood and this may result in digitalis toxicity.
- Corticosteroids may cause hypokalemia if they are used with spironolactone.
- The blood pressure lowering and diuretic effects of furosemide may be reduced or abolished when concomitantly used with indomethacin and other NSAIDs.
- Furosemide may increase the ototoxicity of aminoglycoside antibiotics.
- Simultaneous administration of sucralfate and furosemide may reduce the natriuretic and anti-hypertensive effect of furosemide.

## OVERDOSAGE

Symptoms of overdosage include drowsiness, mental confusion, dizziness, diarrhea and vomiting etc. due to excessive diuresis.

## PHARMACEUTICAL PRECAUTION

Store in dry place, protected from light. Keep out of reach of children.

## PACKAGING

**Edenil<sup>®</sup> 20 tablet:** Box containing 5 strips of 10 tablets each. Each film coated tablet contains furosemide BP 20 mg and spironolactone BP 50 mg.

**Edenil<sup>®</sup> 40 tablet:** Box containing 5 strips of 10 tablets each. Each film coated tablet contains furosemide BP 40 mg and spironolactone BP 50 mg.

**SK+F**

Manufactured by  
**ESKAYEF PHARMACEUTICALS LTD.**  
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