

### Composition

**Lesal Syrup (60 ml and 100 ml):** Each 5 ml syrup contains Levosalbutamol Sulphate INN equivalent to Levosalbutamol 1 mg.

### Pharmacology

Levosalbutamol is the R-isomer of racemic Salbutamol having  $\beta_2$  agonist activity. Levosalbutamol is an effective bronchodilator whose primary mechanism of action is not inhibited by S-Salbutamol. Thus, when compared with racemic Salbutamol, clinically comparable bronchodilation can be achieved with doses that substantially lessens  $\beta$ -mediated side effects.

### Indication

Levosalbutamol is indicated for the relief of bronchospasm in conditions such as asthma and COPD in adults, adolescents, and children 6 years of age and older.

### Dose & Administration

Adults and adolescents above 12 years: 5-10 ml (1-2 mg) three times daily. Children (6-11 years): 5 ml (1 mg) three times daily.

### Contraindication

Levosalbutamol is contraindicated in patients with a history of hypersensitivity to this compound or any of the components of this formulation.

### Precaution

Potentially serious hypokalaemia may result from  $\beta_2$  agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations. Levosalbutamol, like all other  $\beta_2$  adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure and/or symptoms. Although such effects are uncommon after administration of Levosalbutamol at recommended doses.

### Side Effect

Potentially serious hypokalaemia may result from  $\beta_2$  agonist therapy. This effect may be potentiated by hypoxia. Particular caution is advised in severe asthma, with monitoring of serum potassium levels. Other side effects such as palpitation, fine tremors of the skeletal muscle (particularly the hand) and muscle cramps may occur. The other likely side effects are gastrointestinal disturbances such as nausea, vomiting, burning substernal or epigastric pain and diarrhoea. In some cases nervousness, headache, dizziness, fatigue and sleeplessness may occur.

### Use in Pregnancy & Lactation

Use of oral Levosalbutamol in pregnant women should be considered only if the expected benefit to the mother is greater than any possible risk to the fetus or the infant. It is not known whether Levosalbutamol is excreted in human milk. Caution should be exercised when Levosalbutamol is administered to a nursing woman.

### Use in Children & Adolescents

This medicine should be used with caution in children. Safety and efficacy are established based on the form of the medicine and age of the patient. All the recommendations should be followed while prescribing this medicine in children. An adult should supervise the use of this medicine in children.

### Drug Interaction

Other short-acting sympathomimetic bronchodilators or epinephrine should be used with caution with Levosalbutamol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.

### Overdose

The expected symptoms with overdosage are those of excessive  $\beta$ -adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under side effects e.g., tachycardia, nervousness, headache, tremor, nausea, dizziness, fatigue and sleeplessness. Hypokalaemia also may occur. Treatment consists of discontinuation of oral Levosalbutamol together with appropriate symptomatic therapy. In the event of serious poisoning, the stomach should be emptied and, if necessary, a  $\beta$ -blocker administered with caution in patients with a history of bronchospasm.

### Storage

Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

### Packaging

**Lesal Syrup (60 ml)** : Each box contains 60 ml Bottle of syrup and a measuring cup.

**Lesal Syrup (100 ml)** : Each box contains 100 ml Bottle of syrup and a measuring cup.