



#### Presentation

Actisal-1<sup>®</sup> tablet: Each film-coated tablet contains Levosalbutamol Sulfate equivalent to Levosalbutamol INN 1 mg.

Actisal-2<sup>®</sup> tablet: Each film-coated tablet contains Levosalbutamol Sulfate equivalent to Levosalbutamol INN 2 mg.

Actisal<sup>®</sup> Syrup: Each 5 ml contains Levosalbutamol Sulfate equivalent to Levosalbutamol INN 1 mg.

#### Indications

Actisal<sup>®</sup> is indicated for the treatment or prevention of bronchospasm in patients with reversible obstructive airway diseases like Bronchial Asthma, Chronic Bronchitis, Emphysema, etc.

#### Dosage and administration

Age	Dosage
Children: 6-11 years	1 mg tablet three times daily or 5 ml syrup three times daily
Adults and adolescents: above 12 years	1-2 mg three times daily or 5-10 ml syrup three times daily

#### Contraindication

Hypersensitivity to any of the components of the formulation. It should not be prescribed with  $\beta$  blocking drugs. Actisal should not be used for prevention of premature labor associated with toxemia of pregnancy or for threatened abortion during the first and second trimester of pregnancy.

#### Precaution

Asthma may deteriorate acutely over a period of hours, or chronically over several days or longer. If the patient needs more dose of oral Levosalbutamol than usual, this may be a marker of destabilization of asthma. In that condition an alternative or additional therapy including corticosteroid should be instituted promptly. Potentially serious hypokalemia may occur. Particular caution is advised as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives (eg. Aminophylline), steroids and diuretics. Levosalbutamol, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effects. Although such effects are uncommon at recommended dose, if occur, the drug may need to be discontinued. Oral Levosalbutamol should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias or hypertension.

#### Drug interactions

1. Beta-blockers: not only block the effect of beta-agonist but also produce severe bronchospasm.
2. Diuretics the ECG changes and/or hypokalemia that may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta agonists.
3. Digoxin: Serum digoxin level may be decreased.
4. Monoamine Oxidase Inhibitors or Tricyclic Antidepressants: The action of Levosalbutamol on the vascular system may be potentiated.

#### Pregnancy

Use of oral Levosalbutamol in pregnant or nursing mothers should be considered only if the expected benefit to the mother is greater than any possible risk to the fetus or the infant.

#### Lactation

It is not known whether Levosalbutamol is excreted in human milk.

#### Side effects

Potentially severe hypokalemia may result from beta-2agonist therapy. Other side effects such as palpitation, fine tremors of the skeletal muscle and muscle cramp may occur. The gastrointestinal disturbances such as nausea, vomiting, epigastric pain and diarrhoea. In some cases nervousness, headache, dizziness, fatigue and sleeplessness may occur.

#### Overdosage


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. Treatment consists of discontinuation of oral Levosalbutamol. In the event of serious poisoning, the stomach should be emptied and, if necessary, a beta-blocker is administered with caution in patients with a history of bronchospasm.

#### Commercial Pack:

Actisal-1<sup>®</sup> tablet : Each box contains 100's tablets in blister pack.

Actisal-2<sup>®</sup> tablet : Each box contains 100's tablets in blister pack.

Actisal<sup>®</sup> syrup : Bottle containing 50 ml & 100 ml syrup.

Manufactured by:  
 **Silva**  
Pharmaceuticals Limited  
Maijdee, Noakhali, Bangladesh