

## COMPOSITION

Levostar ® 1 Tablet: Each tablet contains Levosalbutamol Sulphate equivalent to Levosalbutamol INN 1 mg.

Levostar ® 2 Tablet: Each tablet contains Levosalbutamol Sulphate equivalent to Levosalbutamol INN 2 mg.

Levostar ® Syrup: Each 5 ml contains Levosalbutamol Sulphate equivalent to Levosalbutamol INN 1 mg.

## DESCRIPTION

Levosalmol is a single isomer b<sub>2</sub>-agonist that differs from racemic salbutamol by elimination of (S)-salbutamol. Levosalbutamol is an effective bronchodilator whose primary mechanism of action is unimpeded by (S)-salbutamol. Thus, when compared with racemic salbutamol, clinically comparable bronchodilation can be achieved with doses that substantially lessen beta-mediated side effects.

## INDICATION

Levostar ® tablets & syrup are indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

## DOSAGE & ADMINISTRATION

Levostar ® 1 & 2 mg Tablets

Adults and adolescents above 12 years: 1-2 mg three times daily.

Children (6 -11 years): 1 mg three times daily.

Levostar ® Syrup

Adults: 5-10 ml three times daily.

Children (6-11 years): 5 ml three times daily

## SIDE EFFECT

Potentially serious hypokalaemia may result from b<sub>2</sub> 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.

## PRECAUTION

Potentially serious hypokalemia may result from b<sub>2</sub> 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-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure. Although such effects are uncommon after administration of Levosalbutamol at recommended doses, if they 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.

#### USE IN PREGNANCY AND LACTATION

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 foetus or the infant.

It is not known whether Levosalbutamol is excreted in human milk. Caution should be exercised when oral Levosalbutamol is administered to a nursing woman.

#### CONTRAINDICATION

Hypersensitivity to any of the components of the formulation.

#### 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

Store at cool and dry place. Protected from light and moisture. Keep out of the reach of children.

#### HOW SUPPLIED

Levostar ® 1 Tablet : Box containing 10 x 10 tablets in blister packs.

Levostar ® 2 Tablet: Box containing 5 x 10 Tablets in blister packs.

Levostar ® Syrup: Each PET bottle contains 50 ml Syrup with a plastic spoon.