

LevostarTM

Levosalbutamol

COMPOSITION

LevostarTM 1 Tablet: Each tablet contains Levosalbutamol 1 mg as Levosalbutamol Sulphate INN.

LevostarTM 2 Tablet: Each tablet contains Levosalbutamol 2 mg as Levosalbutamol Sulphate INN.

LevostarTM Syrup: Each 5 ml syrup contains Levosalbutamol 1 mg Levosalbutamol Sulphate INN.

INDICATION

LevostarTM 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

LevostarTM 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.

LevostarTM 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 β_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.

PRECAUTION

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

LevostarTM Tablet: Store below 30°C. Protect from light and moisture. **LevostarTM Syrup:** Store below 30°C. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

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

LevostarTM 2 Tablet: Box containing 5 x 10 tablets in blister packs.

LevostarTM Syrup: Each PET bottle contains 50 ml syrup with a measuring cup.

LevostarTM Syrup: Each PET bottle contains 100 ml syrup with a measuring cup.

Manufactured by



SQUARE

PHARMACEUTICALS LTD.
BANGLADESH