

Levostar[®] Inhaler

COMPOSITION

Each single actuation delivers Levosalbutamol Sulphate equivalent to Levosalbutamol INN 50 mcg

DESCRIPTION

Levosalbutamol is a single isomer β_2 -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[®] is indicated for the treatment or prevention of bronchospasm in adults, adolescents and children 4 years of age and older with reversible obstructive airway disease

DOSAGE & ADMINISTRATION

For the relief of acute episodes of bronchospasm

Adults and children above the age of 4 yrs.

1 or 2 puffs as necessary

To prevent allergen or exercise-induced bronchospasm

Adults and children above the age of 4 yrs.:

2 puffs 15 minutes prior to exercise, or exposure to allergen, the maximum dose is 8 puffs in 24 hours.

SIDE EFFECTS

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

Levosalbutamol, like all other beta-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, 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

Administration of the drug during pregnancy should be considered only if the expected benefit to the mother is greater than any possible risk to the foetus.

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 receptor stimulation e.g., tachycardia, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, and sleeplessness. Hypokalemia also may occur. Treatment consists of discontinuation of levosalbutamol together with appropriate symptomatic therapy.

The judicious use of cardioselective beta receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm.

STORAGE:

The Inhaler should be stored below 30[°] C, protected from direct sunlight and heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eyes. Keep out of reach of children.

HOW SUPPLIED

Levostar[®] : Each puff delivers 50 mcg of Levosalbutamol, 200 puffs.