

Respira®

Levosalbutamol

Tablet/Syrup

Description

Respira® (Levosalbutamol Sulphate INN) is a single isomer β_2 -agonist that differs from racemic salbutamol by elimination of (S)-salbutamol. Respira® is an effective bronchodilator whose primary mechanism of action is unimpeded by (S)-salbutamol. Thus it can be used in doses that are half of that of racemic salbutamol.

Indications

Respira® 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 and Administration

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

Contraindications

Hypersensitivity to any of the components of the formulations.

Adverse Effects

Potentially serious hypokalemia 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. In few cases nervousness, headache, dizziness, fatigue and sleeplessness have also been reported.

Precautions

Asthma may deteriorate acutely over a period of hours, or chronically over several days or longer. If the patient needs more doses of oral Levosalbutamol than usual, this may be a marker of destabilization of asthma and requires

re-evaluation of the patient and the treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment eg. corticosteroids. Potentially serious hypokalemia may result from β_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-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.

Drug Interactions

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.

Beta-blockers : Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-agonists such as Levosalbutamol, but may also produce severe bronchospasm in asthmatic patients. However, under certain circumstances, e.g. as prophylaxis after myocardial infarction, use of beta-adrenergic blocking agents could be considered, although they should be administered with caution.

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. Hence, caution is advised in the coadministration of beta-agonists with non-potassium sparing diuretics.

Digoxin : Mean decreases of 16% and 22% in serum Digoxin levels were demonstrated after single-dose intravenous and oral administration of racemic salbutamol, hence it is advisable to carefully evaluate the serum Digoxin levels in patients who are currently receiving Digoxin and Levosalbutamol.

Monoamine Oxidase Inhibitors or Tricyclic Antidepressants : Levosalbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of Levosalbutamol on the vascular system may be potentiated.

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 fetus.

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

Commercial Pack

Respira® 1 tablet : Box containing 100 tablets in 10 X 10's blister strips. Each tablet contains Levosalbutamol Sulphate INN equivalent to Levosalbutamol 1 mg.

Respira® 2 tablet : Box containing 100 tablets in 10 X 10's blister strips. Each tablet contains Levosalbutamol Sulphate INN equivalent to

Levosalbutamol 2 mg.

Respira® Syrup : Bottle contains 100 ml of syrup. Each 5 ml contains Levosalbutamol Sulphate INN equivalent to Levosalbutamol 1 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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