

Only for the use of medical professional

Brodil[®] Levo

Levosalbutamol

Description

Brodil[®] Levo is the preparation of Levosalbutamol. 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.

Indications and Uses

Brodil[®] Levo are indicated for the treatment of prevention or bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

Dosage and Administration

Brodil[®] Levo 1mg & 2 mg Tablets

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

Brodil[®] Levo Syrup

Adults: 5-10 ml three times daily.

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

Children (2-5 Years): 2.5 ml three times daily.

Contraindications

Brodil[®] Levo is contraindicated in patients with a history of hypersensitivity to any of the components of the formulation.

Precautions

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 should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias or hypertension.

Side effects

The most frequent side effects are 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.

Pregnancy & 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.

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.
- **Diuretics:** 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:** 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.

Overdosage

The expected symptoms with overdosage are 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.

Pharmaceutical Precautions

Store in a cool & dry place. Protect from light & moisture.

Presentation

Brodil [®] Levo 1 mg tablets	: Each tablet contains Levosalbutamol 1 mg as Sulphate INN.
Brodil [®] Levo 2 mg tablets	: Each tablet contains Levosalbutamol 2 mg as Sulphate INN.
Brodil [®] Levo Syrup	: Each 5 ml contains Levosalbutamol 1 mg as Sulphate INN.

Package quantities

Brodil [®] Levo 1 mg tablets	: Carton of 100 tablets in blister.
Brodil [®] Levo 2 mg tablets	: Carton of 100 tablets in blister.
Brodil [®] Levo Syrup	: Bottle of 100 ml & 50 ml.

® Registered Trade Mark



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