

## **ALBUTAMOL TABLET**

### **Composition**

Each **ALBUTAMOL Tablet** contains:

Salbutamol sulphate equivalent to salbutamol	2 mg
Etofylline	200 mg
Bromhexine hydrochloride	8 mg

### **Pharmacology**

The primary action of b-adrenergic drugs, including salbutamol, is to stimulate adenylase cyclase, the enzyme that catalyzes the formation of cyclic adenosine monophosphate (cAMP) from adenosine triphosphate (ATP) in b-adrenergic cells. The cAMP thus formed mediates the cellular responses. Increased camp levels are associated with relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells. Salbutamol is a selective b<sub>2</sub>-adrenoceptor agonist. At therapeutic dose it acts on the b<sub>2</sub>-adrenoreceptors of pulmonary bronchial muscle with little or no action on the  $\beta$ <sub>1</sub>- adrenoreceptors of cardiac muscle. Activation of the b<sub>2</sub>- adrenoreceptors opens ATPase channels and drives potassium from the extracellular to the intracellular space. This will decrease extracellular hyperkalaemia and increase intracellular potassium thus decreasing the likelihood of arrhythmia. Etophylline is a derivative of theophylline with similar actions. Etofylline has two distinct actions in the airways of patients with reversible obstruction; smooth muscle relaxation (bronchodilation) and suppression of the response of the airways to stimuli (non-bronchodilator prophylactic effects). Etofylline-induced bronchodilatation is mediated by the inhibition of two phosphodiesterase (PDE) isozymes (PDE III and to a lesser extent, PDE IV) while non-bronchodilator prophylactic actions are probably mediated through one or more different molecular mechanisms. Bromhexine hydrochloride is a mucolytic agent, which liquifies thick, tenacious sputum. Viscosity of sputum is reduced by dissolving mucopolysaccharide fibres. It also improves mucocilliary clearance of secretions.

**ALBUTAMOL** is well absorbed from the gastrointestinal tract.

### **Indications**

**ALBUTAMOL Tablet** is indicated for the relief of bronchospasm in adults and children 6 years of age and older with reversible obstructive airway disease due to asthma or chronic bronchitis.

## Contraindications

**ALBUTAMOL tablet** is contraindicated in patients with known hypersensitivity to the ingredients of formulation.

**ALBUTAMOL tablet** is also contraindicated in patients with thyrotoxicosis.

## Precautions

ALBUTAMOL is to be used with caution in patients with hepatic impairment, chronic lung disease, cardiac failure, high fever, hyperthyroidism, hypertension, arrhythmias, diabetes mellitus, convulsive disorders, history of peptic ulcers and pulmonary oedema, and in those taking monoamine oxidase (MAO) inhibitors or tricyclic antidepressants (TCAs). **Safety and effectiveness of ALBUTAMOL in children below 2 years of age have not been established.**

## Pregnancy & Lactation

There are no adequate and well-controlled trials with **ALBUTAMOL** in pregnant and lactating women. Therefore, it should be used only when clearly needed.

## Drug Interactions

Other sympathomimetic bronchodilators or epinephrine should not be used concomitantly with salbutamol, since their combined effect on the cardiovascular system may be deleterious to the patient. Salbutamol should be administered with caution in patients being treated with MAO inhibitors or TCAs, since the action of salbutamol on the vascular system may be potentiated. Concomitant use of propranolol, cimetidine, erythromycin, allopurinol, verapamil, diltiazem and quinolone group of antibacterials may increase etofylline plasma levels. Plasma concentrations are reduced by rifampicin, phenobarbitone, phenytoin, carbamazepine, sulphinpyrazone and smoking.

## Adverse Reactions

The common adverse events that may occur with the use of **ALBUTAMOL** include angina, tremor, muscle cramps, palpitations, headache, anorexia, nausea, anxiety, nervousness, irritability, insomnia, heartburn, gastritis and a transient rise in serum aminotransferase values. High doses can cause neurotoxicity and seizures.

## Dosage & Administration

The usual recommended dose of **ALBUTAMOL Tablet** in adults is 1-2 tablets *tid-qid*.

## Presentation

**ALBUTAMOL Tablet** is available in a blister of 10 tablets.