

SALBUTAMOL

Tablets 4mg

Via Oral

Composition: Each tablet not coated contains:

Sulfato de Salbutamol B.P.	
Eq. a Salbutamol	4mg
Excipients	qs

MECHANISM OF ACTION:

Salbutamol is a beta-adrenergic agonist that exerts a selective action on beta-2 adrenergic receptors in the smooth muscles of the bronchi. At therapeutic doses, it acts on the beta-2 adrenoceptors of the bronchial musculature, causing short-acting bronchodilation (4 to 6 hours) in cases of reversible airway obstruction. The medication also induces vasodilation, which leads to a reflex chronotropic effect and generalized metabolic effects, including hypokalemia.

PHARMACOKINETICS:

Intravenously administered salbutamol has a half-life of 4 to 6 hours; it is eliminated partly via the renal route and partly through metabolism as the 4'-O-sulfate metabolite (phenolic sulfate), which is also excreted primarily in the urine. Feces constitute a minor route of excretion. The majority of a salbutamol dose administered intravenously, orally, or by inhalation is excreted within 72 hours. Plasma protein binding of salbutamol is 10%. Following oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism, yielding the phenolic sulfate. Both the unchanged compound and the conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is 50%.

INDICATIONS: Control of asthma and chronic bronchitis.

ADVERSE EFFECTS:

Tachycardia (increased heart rate), palpitations, headaches, and muscle cramps frequently occur in some patients. Rarely, potentially severe hypokalemia (decreased blood potassium levels), cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia, and extrasystoles), and peripheral vasodilation may occur. Very rarely, hypersensitivity reactions (including angioedema, urticaria, bronchospasm, hypotension, and collapse), hyperactivity, and a sensation of muscle tension have been reported.

PRECAUTIONS AND WARNINGS:

In cardiovascular diseases—such as hypertension, coronary artery disease, and myocardial insufficiency—as well as in arrhythmias and in patients taking digitalis or diuretics. In patients with diabetes mellitus and during pregnancy. In asthmatic patients, tolerance may develop; in such cases, alternative therapy should be instituted.

DRUG INTERACTIONS:

The effects of salbutamol may be enhanced by the concomitant administration of aminophylline or other xanthines. Propranolol and other beta-blockers antagonize the effects of salbutamol.

DOSAGE:

As directed by a physician.

Children aged 2 to 6 years: 1 to 2 mg, three or four times daily.

Children over 6 years of age: 2 mg, three or four times daily.

Adults: 2 to 4 mg, three or four times daily. Some patients may require doses up to 8 mg. For elderly patients, lower initial doses should be used.

STORAGE: Store below 30°C in a dry place; protect from light.

PRESENTATION: Blister pack of 100 tablets.

Keep out of reach of children.

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