

SABULIN®

Salbutamol Tablets/Syrup

Composition:

Syrup: Each 5ml contains Salbutamol (as Sulphate) BP 2mg/5ml

Tablets: Each tablet contains Salbutamol (as Sulphate) BP 4mg

Contains: Lactose

Pharmacological Actions:

Salbutamol is a direct-acting sympathomimetic with mainly beta-adrenergic activity and a selective action on beta₂ receptors. This results in its bronchodilating action being more prominent than its effect on the heart. The sympathetic nervous system plays a role in the regulation of bronchomotor tone and beta₂-adrenoceptors in bronchial smooth muscle produce bronchodilatation when stimulated. This makes short-acting selective agonists of beta₂-adrenoceptors (beta₂ agonists; beta₂ stimulants), of which salbutamol is the paradigmatic example, first-line drugs for the relief of asthma symptoms. They are also widely used in the management of chronic obstructive pulmonary disease, although antimuscarinic bronchodilators may be preferred or used in addition. Long-acting beta₂ agonists are used in asthma in patients also requiring anti-inflammatory therapy.

Pharmacokinetics:

Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first-pass metabolism in the liver and possibly in the gut wall; the main metabolite is an inactive sulfate conjugate. Salbutamol is rapidly excreted in the urine as metabolites and unchanged drug; there is some excretion in the faeces. Salbutamol does not appear to be metabolized in the lung, therefore its ultimate metabolism and excretion after inhalation depends upon the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. It has been suggested that most of an inhaled dose is swallowed and absorbed from the gut. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

Indication:

Salbutamol and salbutamol sulfate are used as bronchodilators in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease. Salbutamol also decreases uterine contractility and may be given as the sulfate to arrest premature labour.

Dosage and Route of Administration:

Adults: The minimum starting dose is 2mg three times a day. The usual effective dose is 4mg three or four times a day, which may be increased to a maximum of 8mg three or four times a day if adequate bronchodilatation is not obtained.

Children: 2 - 6 years: the minimum starting dose is 1mg as 2.5ml of syrup three times daily. This may be increased to 2mg as 5ml of syrup three or four times daily. 6-12 years: the minimum starting dose is 2mg as 5ml syrup three times daily. This may be increased to four times daily. Over 12 years: the minimum starting dose is 2mg three times daily given as 5ml syrup. This may be increased to 4mg as 10ml syrup three or four times daily.

Contra-indication:

Salbutamol oral preparations are contra-indicated in patients with a history of hypersensitivity to any of their components.

Special Warning and Special Precaution:

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment including lung function testing as patients are at risk of severe attacks and even death. Physicians should consider using oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in those patients.

Administration in Pregnancy:

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

Side Effects:

Immune system disorders-Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse. Metabolism and nutrition disorders -Rare: Hypokalaemia. Potentially serious hypokalaemia may result from beta agonist therapy. Nervous system disorders- Very common: Tremor. Common: Headache. Very rare: Hyperactivity.

Cardiac disorders - Common: Tachycardia. Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorders-Rare: Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders -Common: Muscle cramps. Very rare: Feeling of muscle tension.

Overdose:

The preferred antidote for overdosage with Salbutamol is a cardio-selective beta-blocking agent but beta-blocking drugs should be used with caution in patients with a history of bronchospasm. Hypokalaemia may occur following overdose with salbutamol.

Serum potassium levels should be monitored.

Presentation:

Syrup: 60ml and 100ml in amber coloured bottles.

Tablets: Blister pack of 10 x 10's in unit boxes and 1000's in plastic jars.

Storage

Sabulin syrup and tablets should be stored below 30°C, in a dry place, protected from light.

Keep out of reach of children.

Manufactured by:



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