

VENTOL

Syrup

Composition

Each Teaspoon (5 ml) contains:

Salbutamol Sulfate equivalent to Salbutamol 2 mg.

Action

Salbutamol is a selective β_2 adrenoceptor agonist. At therapeutic doses, it acts on the β_2 receptors of bronchial muscle, with little or no action on the β_1 adrenoceptors of cardiac muscle.

Pharmacokinetics

Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O- sulphate (phenolic sulphate) which is also excreted primarily in the urine.

The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

Indications

Ventol is indicated as a bronchodilator in the treatment of bronchospasm associated with bronchial asthma, emphysema and chronic bronchitis.

Contraindications

- Salbutamol should not be taken together with beta-blocking agents.
- Hyperthyroidism and cardiac disease.
- Safety in pregnant and lactating women has not been established.
- Salbutamol is not indicated for the prevention of premature labour associated with toxemia of pregnancy or ante partum haemorrhage, nor should it be used for threatened abortion during the first and second trimesters of pregnancy.
- Salbutamol may interact with mono-amine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days after stopping treatment.

Warnings

Tolerance may develop in asthmatic patients given Salbutamol. If tolerance develops and the patient's condition worsens, alternative or additional therapy should be instituted. The dosage of Salbutamol should not be increased in these cases.

Salbutamol should be avoided or used with care in patients undergoing anaesthesia with any halogenated anaesthetics

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing Mothers

It is unknown whether this drug is excreted in human milk a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Adverse Reactions

The most frequent adverse reactions to Salbutamol in adults and older children were tremor, nervousness, and shakiness; other reported adverse reactions were headache, dizziness, increased appetite, hyperactivity, excitement, tachycardia, epistaxis, and sleeplessness. The following adverse effects each occurred in less than 1 of 100 patients; muscle spasm, disturbed sleep, epigastric pain, cough, palpitations stomach ache, irritable behavior, dilated pupils, sweating, chest pain, and weakness.

Precautions

Salbutamol should be used with caution in patients with hyperthyroidism, cardiovascular disease, occlusive vascular disorders, hypertension, or aneurysms.

Hypokalaemia associated with high doses of salbutamol may result in increased susceptibility to digitalis-induced cardiac arrhythmias.

Tachyphylaxis with resistance may occur with prolonged use of high dosage. Care is necessary when treating patients with diabetes mellitus or closed-angle glaucoma, and in those receiving antihypertensive therapy.

It is important to avoid excessive doses as this is thought to be linked to sudden death probably due to the induction of ventricular arrhythmias.

Drug Interactions

The adverse effects of high doses of Salbutamol may be exacerbated by concomitant administration of high doses of corticosteroids.

The effects of Salbutamol are antagonized by propranolol and other β -adrenoceptor blocking agents and enhanced by aminophylline or other xanthines.

An increased risk of arrhythmias may occur if patients are receiving cardiac glycosides, quinidine, or tricyclic antidepressants. Interaction with alpha- and beta-blocking agents may occur.

Dosage and Administration

Syrup

For children 2 to 6 years of age: dosing should be initiated at 0.1 mg/kg body weight three times a day, but not to exceed 2 teaspoons given three times a day.

Over 6 years: 5 ml three to four times daily.

Adults: 5 - 10 ml three to four times daily.

Some patients may require dosages of up to 20 ml.

Elderly patients should be given the lower dose initially.

Over Dosage

Fine tremor of skeletal muscles, tachycardia, palpitations, and peripheral vasodilation. Treatment is symptomatic and supportive.

Presentation

Ventol syrup

Bottle of 150 ml.