

Salbutamol (as Sulphate) BP 200 mcg

COMPOSITION

Each capsule contains microfine Salbutamol (as Sulphate) BP 200 mcg .

PHARMACOLOGY

Salbutamol is a selective β_2 -adrenoceptor agonist. At therapeutic doses, it acts on the β_2 -adrenoceptors of bronchial smooth muscle, with little or no action on the β_1 -adrenoceptors of cardiac muscle. Salbutamol provides short acting (4-6 hours) bronchodilatation with a fast onset (within 5 minutes) in reversible airways obstruction. It also has an anti-inflammatory effect on mast cells causing inhibition of release of bronchoconstrictor mediators including histamine, neutrophil chemotactic factor (NCF) and prostaglandin D_2 .

INDICATIONS

Salbutamol Rotacaps are particularly suitable for the relief of asthma symptoms. It is valuable as relief medication in mild, moderate and severe asthma.

DOSAGE AND ADMINISTRATION

Route of administration : Oral Inhalation

The capsule is to be inserted into the ^{ACME[®]} Easyhaler device for use. So, the capsule will be pierced and ready to be used.

Adults : 200-400 mcg (one to two rotacaps) daily; for persistent symptoms up to 3-4 times daily.

Children : 200 mcg (one rotacap) daily

Prophylaxis in exercise-induced bronchospasm

Adults : 400 mcg (two rotacaps) daily

Children : 200 mcg (one rotacap) daily

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Inhaled Salbutamol is not appropriate for managing premature labour. It should not be used for threatened abortion. Salbutamol Rotacaps are contraindicated to patients with a history of hypersensitivity to any of the components or to the patients using β -blocking drugs.

WARNING & PRECAUTIONS

Patients should be instructed with the proper use of ^{ACME[®]} Easyhaler to ensure that the drug reaches the target areas within the lungs. A capsule should only be inserted into the ^{ACME[®]} Easyhaler immediately prior to use. Unnecessary administration of the drugs during the first trimester of pregnancy should be avoided. Caution is advised to patients suffering from thyrotoxicosis.

SIDE-EFFECTS

Common Side effects : Fine tremor of skeletal muscle occurs in some patients, usually the hands are most obviously affected. This effect is not dose related. Sometimes stimulation may be exposed to the action of salbutamol on skeletal muscle which is not due to direct CNS stimulation. Headaches have occasionally been reported. Hoarseness of mouth and throat irritation may occur.

Rare Side effects : Angioedema, urticaria, bronchospasm, hypotension, muscle cramps, tachycardia have been reported very rarely.

USE IN PREGNANCY AND LACTATION

Use in Pregnancy : As there are no adequate and well-controlled studies of Salmolin Rotacap or Salbutamol Sulfate in pregnant women, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Lactation : It is not known whether the components of Salmolin Rotacap are excreted in human milk. Caution should be exercised when Salmolin Rotacap is administered to a nursing woman.

USE IN CHILDREN AND ADOLESCENTS

Use of this preparation is safe & effective as per dosage guideline.

DRUG INTERACTIONS

With medicine : Salbutamol and non-selective beta-blocking drugs such as propranolol should generally not be prescribed together. 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 concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

With food and others : No data is found on interaction with food of this medicine.

OVERDOSE

The signs and symptoms of Salbutamol overdose are tachycardia and muscle tremor.

PHARMACEUTICAL PRECAUTIONS

- Rotacap is to be used through ^{ACME[®]} Easyhaler.
- Rotacap is not to be swallowed.
- Do not exceed the recommended dose.
- Insert the Rotacap in the ^{ACME[®]} Easyhaler just prior to use, as Rotacap exposed to moisture may not be pierced easily.

STORAGE

Keep all medicines out of reach of children.

Store below 30^o C and dry place, protected from light.

PACKING

Each box contains 3x10 capsules (Rotacap) in Alu-Alu blister strips.

*Further information is available on request



Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness