

# Salomax<sup>®</sup>

Salbutamol Sulfate BP Inhalation Capsules

## DESCRIPTION

**Salomax<sup>®</sup>** inhalation capsule is used for dry powder inhaler. It is intended for oral inhalation only. It contains Salbutamol (as Salbutamol Sulfate BP) as the active ingredient which is used in the treatment of bronchial asthma and reversible obstructive airway disease. Salbutamol is relatively selective  $\beta$ -2-adrenoreceptor stimulant.

## PHARMACOLOGY

Salbutamol sulfate is a  $\beta$ -2-adrenergic agonist. The pharmacologic effects of Salbutamol Sulfate are attributable to activation of  $\beta$ -2-adrenergic receptors on airway smooth muscle. Activation of  $\beta$ -2-adrenergic receptors leads to the activation of adenylyl cyclase and to an increase in the intracellular concentration of cyclic-3',5'-adenosine monophosphate (cyclic AMP). This increase of cyclic AMP is associated with the activation of protein kinase A, which in turn inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in muscle relaxation.

## INDICATIONS

**Salomax<sup>®</sup>** inhalation capsule is indicated for the treatment and prophylaxis of bronchial asthma and for the treatment of reversible airways obstruction associated with bronchitis and emphysema; status asthmaticus; prophylactic therapy before exertion or to prevent exercise-induced asthma.

It is suitable for treating bronchospasm in patient with coexisting heart disease or hypertension, including those taking beta blockers, because of its selective action on the bronchial receptors and lack of effects on the cardiovascular system. It has highly selective action on beta adrenergic receptors in bronchial muscle.

**Pediatrics (<4 years of age):** The safety and efficacy in children below the age of 4 years has not been established.

## DOSAGE AND ADMINISTRATION

- **Treatment or prevention of bronchospasm in adults and children 4 years of age and older:** 2 inhalations every 4 to 6 hours. In some patients, 1 inhalation every 4 hours may be sufficient.
- **Prevention of exercise-induced bronchospasm in adults and children 4 years of age and older:** 2 inhalations 15 to 30 minutes before exercise.
- Turbohaler does not require priming.
- Do not use with a spacer or volume holding chamber.
- Keep the inhaler clean and dry at all times. Routine maintenance is not required. If the mouthpiece needs cleaning, gently wipe the mouthpiece with a dry cloth or tissue as needed. Never wash or put any part of the inhaler in water.

## CONTRAINDICATIONS

- Patients with hypersensitivity to Salbutamol. • Patients with severe hypersensitivity to milk proteins.

## SIDE EFFECTS

Most common side effects are back pain, pain, gastroenteritis viral, sinus headache, urinary tract infection, nasopharyngitis, oropharyngeal pain and vomiting.

## WARNINGS AND PRECAUTIONS

- Life-threatening paradoxical bronchospasm may occur. Discontinue Salbutamol immediately and treat with alternative therapy.
- Need for more doses of Salbutamol than usual may be a sign of deterioration of asthma and requires reevaluation of treatment.
- Salbutamol is not a substitute for corticosteroids.
- Cardiovascular effects may occur. Use with caution in patients sensitive to sympathomimetic drugs and patients with cardiovascular or convulsive disorders.
- Excessive use may be fatal. Do not exceed recommended dose.
- Immediate hypersensitivity reactions may occur. Discontinue Salbutamol immediately. Hypokalemia and changes in blood glucose may occur.

## USE IN PREGNANCY AND LACTATION

Although there is no evidence that salbutamol is teratogenic, it can be used in first trimester only if absolutely essential. It is pregnancy category C. Salbutamol probably enters breast milk, but the concentration is unknown.

However, no adverse effects have been reported in the breast-fed babies of months taking the drug by inhalation.

## DRUG INTERACTION

- **Other short-acting sympathomimetic aerosol bronchodilators and adrenergic drugs:** May potentiate effect.
- **Beta-blockers:** May decrease effectiveness of Salbutamol and produce severe bronchospasm. Patients with asthma should not normally be treated with beta-blockers.
- **Diuretics, or non-potassium sparing diuretics:** May potentiate hypokalemia or ECG changes. Consider monitoring potassium levels.
- **Digoxin:** May decrease serum digoxin levels. Consider monitoring digoxin levels.
- **Monoamine oxidase (MAO) inhibitors and tricyclic antidepressants:** May potentiate effect of Salbutamol on the cardiovascular system. Consider alternative therapy in patients taking MAOs or tricyclic antidepressants.

## OVERDOSE

The expected symptoms with overdosage are those of excessive  $\beta$ -adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under side effects, e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats per minute, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and insomnia.

Hypokalemia may also occur. As with all sympathomimetic medications, cardiac arrest and even death may be associated with abuse of Salbutamol.

Treatment consists of discontinuation of Salbutamol together with appropriate symptomatic therapy. The judicious use of a cardio selective  $\beta$ -receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of Salbutamol.

## PHARMACEUTICAL PRECAUTION

**Salomax<sup>®</sup>** Inhalation capsules must not be swallowed. Only to be used with Turbohaler. Keep away from light and wet place.

Store at or below 25 °C temperature. Keep out of reach of children. Remove Inhalation capsule from the blister pack only immediately before use it in the Turbohaler as Inhalation capsule exposed to moisture may not be pierced easily.

## METHOD OF ADMINISTRATION

Please see opposite side of this leaflet.

## PACKAGING

**Salomax<sup>®</sup> Inhalation Capsules:**

Box containing 3 strips of 10 capsules each. Each capsule contains Salbutamol Sulfate BP equivalent to Salbutamol 200 mcg.

**SK+F**

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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