

# Sulprex<sup>®</sup> MDI

Salbutamol + Ipratropium Bromide

## Description:

Sulprex<sup>®</sup> Inhalation Aerosol is a combination of the anti-cholinergic bronchodilator, Ipratropium bromide, and the  $\beta_2$  adrenergic bronchodilator, Salbutamol.

## Composition:

Each single actuation of Sulprex<sup>®</sup> delivers 20 mcg of Ipratropium bromide BP and 100 mcg of Salbutamol BP.

## Indications:

Sulprex<sup>®</sup> Inhalation Aerosol is indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.

**Dosage and Administration:** The dose of Sulprex<sup>®</sup> Inhalation Aerosol is two inhalations four times a day. Patients may take additional inhalations as required; however, the total number of inhalations should not exceed 12 in 24 hours. Safety and efficacy of additional doses of Sulprex<sup>®</sup> Inhalation Aerosol beyond 12 puffs in 24 hours have not been studied. Also, safety and efficacy of extra doses of Ipratropium or Salbutamol in addition to the recommended doses of Sulprex<sup>®</sup> Inhalation Aerosol have not been studied. It is recommended to "test spray" three times before using for the first time and in cases where the aerosol has not been used for more than 24 hours.

**Contraindications:** Salbutamol & Ipratropium Bromide combination Inhalation Aerosol is contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soybean and peanut. Salbutamol & Ipratropium Bromide combination Inhalation Aerosol is also contraindicated in patients hypersensitive to any other components of the drug product or to atropine or its derivatives.

**Precautions:** Effects Seen with Anticholinergic Drugs: Salbutamol & Ipratropium Bromide combination Inhalation Aerosol contains ipratropium bromide and therefore, should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction. Effects Seen with Sympathomimetic Drugs: Preparations containing sympathomimetic amines such as Salbutamol sulfate should be used with caution in patients with convulsive disorders, hyperthyroidism or diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines. Beta-adrenergic agents may also produce significant hypokalemia in some patients (possibly through intracellular shunting) which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Use in Hepatic or Renal Disease: Salbutamol & Ipratropium Bromide combination Inhalation Aerosol has not been studied in patients with hepatic or renal insufficiency. It should be used with caution in those patient populations.

**Pregnancy & Lactation:** Ipratropium bromide: Pregnancy category B. Salbutamol: Pregnancy Category C. There are, however, no adequate and well-controlled studies of Salbutamol & Ipratropium Bromide combination Inhalation Aerosol in pregnant women. Because animal reproduction studies are not always predictive of human response,

Salbutamol & Ipratropium Bromide combination Inhalation Aerosol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Labor and Delivery: Because of the potential for  $\beta_2$ -agonist interference with uterine contractility, use of Salbutamol & Ipratropium Bromide combination Inhalation Aerosol for the treatment of COPD during labor should be restricted to those patients in whom the benefits clearly outweigh the risk.

**Nursing Mothers:** It is not known whether the components of Salbutamol & Ipratropium Bromide combination Inhalation Aerosol are excreted in human milk. However, because many drugs are excreted in human milk, caution should be exercised when Salbutamol & Ipratropium Bromide combination Inhalation Aerosol is administered to a nursing mother.

**Side Effects:** Adverse reactions, includes edema, fatigue, hypertension, dizziness, nervousness, paresthesia tremor, dysphonia, insomnia, diarrhea, dry mouth, dyspepsia, vomiting, arrhythmia, palpitation, tachycardia, arthralgia, angina, increased sputum taste perversion, and urinary tract infection/dysuria. Allergic-type reactions such as skin rash, angioedema of tongue, lips and face; urticaria (including giant urticaria), laryngospasm and anaphylactic reaction have been reported, with positive rechallenge in some cases. Many of these patients had a history of allergies to other drugs and/or foods including soybean. Other rare side-effects include cases of precipitation or worsening of narrow-angle glaucoma, acute eye pain, blurred vision, nasal congestion, drying of secretions, mucosal ulcers, irritation from aerosol, paradoxical bronchospasm, wheezing, exacerbation of COPD symptoms, heartburn, drowsiness, CNS stimulation, coordination difficulty, weakness, itching, flushing, alopecia, hypotension, gastrointestinal distress constipation, and urinary difficulties.

**Overdosage:** The effects of overdosage are expected to be related primarily to Salbutamol sulfate. Acute overdosage with ipratropium bromide is unlikely since ipratropium bromide is not well absorbed systemically after aerosol or oral administration. Manifestations of overdosage with Salbutamol may include anginal pain, hypertension, hypokalemia, tachycardia with rates up to 200 beats per minute and exaggeration of the pharmacologic effects. As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with abuse. Dialysis is not appropriate treatment for overdosage of Salbutamol as an inhalation aerosol; the judicious use of a cardiovascular  $\beta$ -receptor blocker, such as metoprolol tartrate may be indicated.

**Pharmaceuticals Precautions:** The Inhaler should be stored in a dry, cool place away from direct sunlight and heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eyes. Keep out of reach of children.

**How Supplied:** Sulprex<sup>®</sup> Inhaler. Each puff delivers 20 mcg of Ipratropium bromide and 100 mcg of Salbutamol, 200 puffs.