

SALPIUM

Salbutamol (as Sulphate) BP & Ipratropium Bromide BP HFA Inhalation Aerosol

CFC FREE

DESCRIPTION

Salpium Inhalation Aerosol is a combination of Salbutamol (as Sulphate) and Ipratropium Bromide. It is a hydrofluoroalkane (HFA) based environment friendly inhaler. Because it does not contain chlorofluorocarbon (CFC) as propellant which is one of the main reasons of ozone layer depletion.

Salbutamol is a short acting beta₂-adrenergic bronchodilator and Ipratropium Bromide is an anticholinergic bronchodilator. When used in combination, Ipratropium Bromide prevents the increase in intracellular concentration of cyclic guanosine monophosphate, which are caused by interaction of acetylcholine with the muscarinic receptor on bronchial smooth muscle. **Salpium Inhalation Aerosol** is expected to maximize the response of the treatment in patients with chronic obstructive pulmonary disease (COPD) by reducing bronchospasm through two distinctly different mechanisms, anticholinergic (parasympatholytic) and sympathomimetic. Simultaneous administration of an anticholinergic (Ipratropium Bromide) and a beta₂-sympathomimetic (Salbutamol) is designed to benefit the patient by producing a greater bronchodilatory effect than when either drug is utilized alone at its recommended dosage.

COMPOSITION

Each actuation delivers Salbutamol (as Sulphate) BP 100 mcg and Ipratropium Bromide BP 20 mcg.

INDICATIONS AND USAGE

Salpium Inhalation Aerosol is indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continues to have evidence of bronchospasm and who requires a second bronchodilator.

DOSE AND ADMINISTRATION

Age	Puffs
Adult dose (Including the elderly)	2 puffs of Salpium 4 times a day (Patients may take additional puffs as required but total number of puffs should not exceed 12 in 24 hours)

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Salpium Inhalation Aerosol is contraindicated in patients with a history of hypersensitivity to Soya-Lecithin or related food products such as soybean and peanut. **Salpium Inhalation Aerosol** is also contraindicated in patients hypersensitive to any other components of the drug product or to atropine or its derivatives.

SIDE EFFECTS

Due to presence of Salbutamol, mild tremor and headache have been reported. These usually disappear with continuous treatment. There have been very rare reports of treatments muscle cramp, hypersensitivity reactions including angioedema, urticaria, bronchospasm and hypotension. For the presence of Ipratropium Bromide headache, influenza, chest pain, nausea, dyspnea, coughing, pharyngitis, sinusitis are rarely reported.

SPECIAL PRECAUTIONS

Salpium Inhalation Aerosol contains Ipratropium Bromide and, therefore, should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction. Preparations containing sympathomimetic amines such as Salbutamol Sulphate should be used

with caution in patients with convulsive disorders, hyperthyroidism, diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines.

USE DURING PREGNANCY AND LACTATION

Ipratropium Bromide: Pregnancy category B. Studies have demonstrated no teratogenic effects as a result of ipratropium. **Salbutamol:** Pregnancy category C. Salbutamol has been shown to be teratogenic in animals. There are, however no adequate and well-controlled studies of **Salpium Inhalation Aerosol** (Salbutamol and Ipratropium Bromide combination) in pregnant woman. **Salpium Inhalation Aerosol** should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus. It is not known whether the components of the **Salpium Inhalation Aerosol** are excreted in human milk. As many drugs are excreted in human milk, **Salpium** should be cautiously administered to a nursing mother.

DRUG INTERACTIONS

Salpium Inhalation Aerosol has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines and steroids, commonly used in the treatment of COPD. No formal drug interaction studies have been performed with **Salpium Inhalation Aerosol** and these or other medications commonly used in the treatment of COPD. Ipratropium Bromide should be co-administered cautiously with other anticholinergic agents and sympathomimetic agents, which may increase the risk of adverse cardiovascular effects. Beta-2-agonist containing drugs, like **Salpium** should be administered with extreme caution to patients with non-potassium sparing diuretics, monoamine oxidase inhibitors or tricyclic antidepressants.

OVERDOSE

The effects of overdosage are expected to be related primarily to Salbutamol Sulphate. Manifestations of overdosage with Salbutamol may include anginal pain, hypertension, hypokalemia and tachycardia.

SUPPLY

Each canister contains 200 metered doses, each dose contains Salbutamol (as Sulphate) BP 100 mcg and Ipratropium Bromide BP 20 mcg.

GENERAL PRECAUTIONS:

Do not puncture, break or incinerate the pressurised canister even when apparently empty.
Avoid storage in direct sunlight or heat.
Store in cool and dry place.
Keep away from children.
Keep away from eyes.

* Further information is available on request.



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