

Salmolin

Respirator Solution

Salbutamol 5 mg/ ml

COMPOSITION

Each ml solution contains Salbutamol sulphate BP equivalent to Salbutamol 5 mg.

PHARMACOLOGY

Salmolin Respirator Solution is an aqueous colourless solution of Salbutamol Suphte BP. Salbutamol is a synthetic sympathomimetic agent with predominant beta-2 adrenergic activity. Salbutamol produces bronchodilation through stimulation of beta-2 adrenergic receptors in bronchial smooth muscle, thereby causing relaxation of bronchial muscle fibres.

INDICATION

Salmolin Respirator Solution is indicated for the treatment of acute Asthma, chronic bronchitis, emphysema and other conditions associated with airways obstruction.

DOSAGE & ADMINISTRATION

By Intermittent Administration

Adult (and the elderly): Salmolin Respirator Solution 0.5-1.0 ml should be diluted to final volume of 2.0-4.0 ml with normal saline for injection. The resulting solution is inhaled from a suitably driven nebulizer until aerosol generation ceases. Using a correctly matched nebulizer and driving source this should take about 10 minutes. Salmolin Respirator Solution may be used undiluted for intermittent administration. For this 2.0 ml of the solution is placed in the nebulizer and the patient allowed to inhale until bronchodilation is achieved. This usually takes 3-5 minutes. Some adult patients may require higher doses of salbutamol upto 10 mg in which case nebulization may continue until aerosol generation ceases.

Children (under 12 years of age): 0.5 ml of the solution diluted to 2.0-4.0 ml with normal saline. Some children patients may however require higher doses upto 1.0 ml of the solution. Intermittent treatment may be repeated four times a day.

By Continuous Administration

Salmolin Respirator Solution is diluted with normal saline for injection, 1-2 ml solution made upto 100 ml with diluent. The diluted solution is administered as an aerosol by a suitably driven nebulizer. The usual rate of administration is 1-2 mg/hour. Delivery of the aerosol may be by face mask or via an endotracheal tube. Intermittent positive pressure may be used but is rarely necessary. When there is risk of anoxia through hypoventilation, oxygen should be added to the inspired air.

Dilution: Salmolin Respirator Solution may be diluted with Sodium Chloride Injection BP (normal saline). Solutions in nebulizer should be replaced daily.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATION

It is contraindicated in patients with a history of hypersensitivity to Salbutamol or any of its components.

WARNING & PRECAUTION

It should be used with care in patients known to have received large doses of other sympathomimetic drugs. It should be used with care in patients suffering from thyrotoxicosis. Salmolin Respiration Solution should be used with a respirator or nebulizer, only under the direction of a physician. Not to be injected or taken orally. Patients receiving treatment at home with Salmolin Respirator Solution should be warned that if either usually relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration but seek medical advice.

SIDE EFFECT

Common side effects: A small increase in heart rate may occur in patients who inhale large doses of Salbutamol. This is not usually accompanied by any change in ECG.

Rare side effects: Other side effects which occur with high doses are peripheral vasodilation, fine tremor of skeletal muscle, muscle cramps, headaches.

USE IN PREGNANCY & LACTATION

Unnecessary administration of drugs during the first trimester of pregnancy is undesirable. It is not known whether this drug is excreted in human milk. Because of the potential of tumorigenicity shown for salbutamol in some animal studies, 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.

USE IN CHILDREN & ADOLESCENTS

Safe using in age 1 month and above for children & adolescents.

DRUG INTERACTION

With medicine : Salbutamol should be administered with extreme caution to patients being treated with MAO inhibitors or tricyclic antidepressants since the action of Salbutamol on the cardiovascular system may be potentiated. Beta-adrenergic blocking drugs, especially the non-cardio selective ones; may effectively antagonize the action of Salbutamol. Mean decreases of 16% to 22% in serum digoxin levels were demonstrated after single dose oral administration of Salbutamol.

With food & others : No data available about interaction with food.

OVERDOSAGE

During continuous administration any signs of over dosage may be counteracted by withdrawal of the drug. The preferred antidote for over dosage is a cardioselective betablocker, but betablockers should be used with caution in patients with a history of bronchospasm.

STORAGE

Protected from light, store below 30° C temperature and dry place. Keep all medicines out of reach of children.

PACKING

Each box contains 20 ml respirator solution in bottle and a syringe.

PHARMACEUTICAL PRECAUTION

Once a bottle has been opened, the contents should be discarded after one month. Product should be used under the direction of a registered physician.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

SALMOLIN

Salbutamol (as Sulphate) BP
HFA Inhalation Aerosol

CFC FREE

DESCRIPTION

Salmolin (Salbutamol) is a beta-2-adrenoreceptor agonist. 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.

Salmolin relaxes the muscles in the walls of small air passages in the lungs. Salbutamol is used in the treatment of asthma and other forms of reversible airways obstruction.

COMPOSITION

Each actuation delivers Salbutamol (as Sulphate) BP 100 mcg.

INDICATION

- For the relief of acute bronchospasm and for managing intermittent episodes of asthma.
- For chronic maintenance or prophylactic therapy of asthma.
- To prevent exercise induced bronchospasm.

DOSAGE AND ADMINISTRATION

Condition	Adults and Elderly dose		Child dose	
	Amount	Puffs	Amount	Puffs
Acute bronchospasm and intermittent episodes of asthma	100 mcg or 200 mcg per day	1 or 2 puffs of SALMOLIN per day	100 mcg per day	1 puff of SALMOLIN per day
Chronic maintenance or prophylactic therapy	200 mcg 3-4 times daily	2 puffs of SALMOLIN 3-4 times daily	100 mcg 3-4 times daily (may be increased to 200 mcg if necessary)	1 puff of SALMOLIN 3-4 times daily (may be increased to 2 puffs if necessary)
Exercise induced bronchospasm	200 mcg before exertion	2 puffs of SALMOLIN before exertion	100 mcg before exertion	1 puff of SALMOLIN before exertion

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATION

Salmolin is contraindicated in patients with the history of hypersensitivity to any of its ingredients.

SPECIAL PRECAUTION

Salmolin, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders especially coronary insufficiency, cardiac arrhythmias and hypertension in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus.

SIDE EFFECTS

There have been very rare reports of side effects in using **Salmolin** Inhaler. Mild tremor and headache have been rarely reported. These usually disappear with continuous treatment.

Transient muscle cramping is observed slightly. Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension etc. have been reported very rarely.

As with other inhalation therapy, the potential for paradoxical bronchospasm should be considered. If it occurs, the preparation should be discontinued immediately and alternative therapy should be instituted.

USE IN PREGNANCY

There are no adequate and well-controlled studies in pregnant women. Salbutamol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

USE IN LABOR AND DELIVERY

Use of **Salmolin** (Salbutamol) Inhalation Aerosol for relief of bronchospasm during labor should be restricted to those patients in whom the benefits clearly outweigh the risk.

USE IN LACTATION

It is not known 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.

DRUG INTERACTION

Other short-acting sympathomimetic aerosol bronchodilators should not be used concomitantly with **Salmolin**. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects. During use of Monoamine Oxidase Inhibitors or Tricyclic Antidepressants, Beta-blockers, Diuretics and Digoxin, patients should use Salmolin cautiously.

SUPPLY

Each canister contains 200 metered doses, each dose contains 100 mcg of Salbutamol (as Sulphate) BP.

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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Dhaka, Bangladesh