

R_x**SALBUTAMOL****BRONCHOSAR**

100 mcg / puff
Metered Dose Inhaler
Anti-asthma
(Bronchodilator)

FORMULATION:

Each puff contains:
Salbutamol, BP..... 100 mcg
(as sulfate)

PRODUCT DESCRIPTION:

Aluminium can contains suspension for inhalation, supplied in crimping, with metering valve and actuator which are held under pressure with suitable propellants or suitable mixtures of liquefied propellants. Salbutamol is a white or almost white crystalline powder.

PHARMACOKINETICS:

Salbutamol is readily absorbed from the gastrointestinal tract. When given by inhalation, 10 to 20% of the dose reaches the lower airways. This remainder is retained in the delivery system or is swallowed and absorbed from the gut. Salbutamol is subject to first-pass metabolism in the liver and possibly in the gut wall but does not to be metabolized in the Lung; the main metabolite is the inactive sulfate conjugate. Salbutamol is rapidly excreted, mainly in the urine, as metabolites and unchanged drug; a smaller proportion is excreted in the faeces. The plasma half-life of Salbutamol has been estimated to range from 4 to 6 hours.

INDICATIONS:

Salbutamol is used as bronchodilators in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease. Salbutamol also decreases uterine contractility and may be given as the sulfate arrest premature labour.

PREGNANCY AND LACTATION:

There are no adequate studies in pregnant women and for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

OVERDOSE AND TREATMENT:

In the case of an overdose, undesirable effects occur very quickly and with increased severity. Typical symptoms are: tachycardia, palpitations, arrhythmia, restlessness, sleep disturbances, chest pain and vigorous tremor, especially on hands but also on the whole body. Nausea, dizziness, increased systolic blood pressure and decreased diastolic blood pressure may also be observed. Occasionally, psychotic reactions were observed after excessive doses of salbutamol.

In the case of a salbutamol overdose there can increasingly be a shift of potassium into the intracellular space resulting in hypokalemia, as well as hyperglycemia, hyperlipidemia, and hyperketonemia. Increased serum lactate levels and rarely, lactic acidosis, have been reported following therapy with salbutamol, particularly after high dose administration. Symptoms include deep, rapid breathing, cold and blue

coloured fingers and toes, inability to concentrate and general malaise. Treatment after an overdose of a sympathomimetic is mainly symptomatic. The following measures may be considered, depending upon the individual circumstances.

If large amounts of the drug are swallowed, irrigation of the stomach should be considered. Activated charcoal and laxatives can have favorable effects on the undesired absorption of the β -sympathomimetic.

For the cardiac symptoms of over dosage with salbutamol a cardio selective beta-blocking agent may be considered, but beta-blocking agent may be considered, but beta-blocking drugs should only be used with caution and be avoided as far as possible in patients with a history of bronchospasm.

ECG monitoring is indicated in such patients. In the case of fairly pronounced lowering of the blood pressure, volume substitution (e.g. plasma expanders) is recommended.

If hypokalemia develops, electrolyte balance should be monitored and, if appropriate, electrolytes may need to be administered.

DOSAGE AND ADMINISTRATION:

For the relief of acute bronchospasm, 1 or 2 inhalations of salbutamol 100 micrograms may be given from a conventional metered-dose aerosol as required, up to 4 times daily. Two inhalations may also be given just before exertion for the prophylaxis of exercise-induced bronchospasm. In acute severe asthma where delivery via nebulizer is not available, 4 to 6 inhalations of salbutamol 100 micrograms from a metered-dose inhaler may be given at intervals of 10 to 20 minutes via a large volume spacer.

Administration in children. For the treatment of reversible airways obstruction, including nocturnal asthma, and prevention of exercise-induced bronchospasm in children

1 month to 18 years of age, 100 or 200 micrograms (1 or 2 inhalations) up to four times daily, for occasional use only.

In the management of acute mild to moderate exacerbation of asthma, salbutamol may be given using a metered-dose aerosol inhaler via a spacer device. For children of all ages, 1 inhalation (100 micrograms) may be given 15 to 30 seconds up to a maximum of 10 inhalations.

ADVERSE EFFECTS:

Salbutamol has mainly β_2 -agonist effects and, like other β_2 -agonist, may cause fine tremor of skeletal muscle (particularly the hands), palpitation, tachycardia, nervous tension, headaches, peripheral vasodilation, and rarely muscle cramps. Inhalation causes fewer adverse effects than systemic dosage, and the more selective β_2 -agonist. Potentially serious hypokalemia has been reported after large doses. Myocardial ischaemia has also been reported. Hypersensitivity reactions have occurred, including paradoxical bronchospasm, angioedema, urticaria, hypotension, and collapse.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.

Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

PRECAUTIONS:

Salbutamol and other beta agonists should be given with cautions in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension and diabetes mellitus (especially on intravenous use – blood glucose should be monitored since ketoacidosis has been reported.) In severe asthma particular caution is also required to avoid inducing hypokalemia as this effect may be potentiated by hypoxia or by the effect of other antiasthma drugs on potassium; plasma-potassium concentrations should be monitored. β_2 -agonist such as salbutamol are not appropriate for use alone in the treatment of more than mild asthma. Increasing need for, or decrease durations effect of inhaled salbutamol and other short acting β_2 -agonist indicates deterioration of asthma control and the likely requirements for increase anti-inflammatory therapy. In a woman being treated for premature labour risk of pulmonary oedema means that the patients state of hydration and cardiac and respiratory function should be mentioned very carefully; the volume of infusion fluid should be kept to the minimum (normally using glucose 5% as the diluents), and β_2 -agonist therapy should be stopped immediately and diuretic therapy started if signs of pulmonary oedema develop. Other risk factors for pulmonary oedema include multiple pregnancy and heart disease. Ischaemic heart disease or significant risk factors for ischaemic heart disease are specific contraindications; where heart disease is suspected assessment by a physician experienced in cardiology is needed. Eclampsia and severe pre-eclampsia are also contraindications, with special care needed in mild to moderate pre-eclampsia. Other contraindications include intra-uterine infection, intra-uterine fetal death, antepartum haemorrhage (which required immediate deliver), placenta praevia, and cord compression; β_2 -agonist should not be used for threatened miscarriage.

DRUG INTERACTIONS:

Use salbutamol and other β_2 -agonist with corticosteroids, diuretics, or xanthenes increase the risk of hypokalemia, and monitoring of potassium concentrations is recommended in severe asthma, where such combinations therapy is common. For an outline of interactions associated with sympathomimetics.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITIONS:

Store at temperature not exceeding 30°C.

AVAILABILITY:

19 mL Aluminium canister (Box of 1's)

FDA Registration No. : DRP-5454
Date of First Authorization : 01 December 2020
Date of Revision of Package Insert : 19 January 2022

Manufactured by:
ARISTOPHARMA LTD.
Plot # 14-22, Road # 11 & 12, Shampur-Kadamtali II/A,
Dhaka-1204, Bangladesh.

Imported and Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave, Phase III, BF Homes
Parañaque City.

20002087/05

Important information for the patients

HFA Inhaler

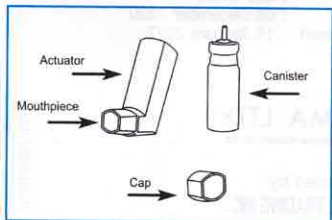
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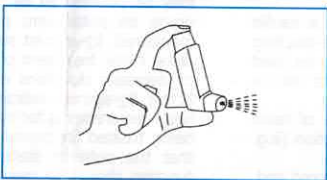
CFC Free

Parts of an inhaler



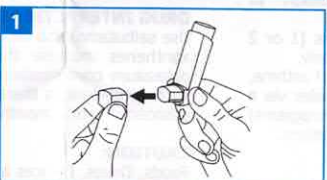
How to use your inhaler correctly?

Test your inhaler

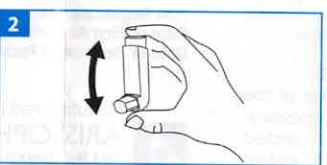


Before using your Inhaler for the first time, or if it has not been used for a week or more, shake it well and then "test fire" it, i.e. release one puff into the air.

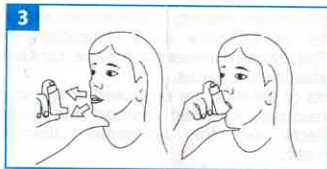
Using your inhaler



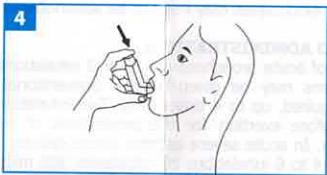
1. Remove the cap from the mouthpiece of the actuator. Make sure there is nothing in the mouthpiece before use.



2. Hold canister as illustrated in figure. Shake the canister vigorously for at least 10 seconds.



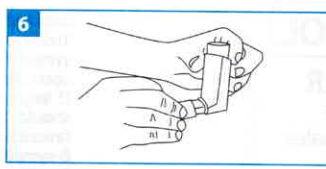
3. Breathe out gently as you can and immediately place the mouthpiece in your mouth between your teeth. Do not bite it.



4. Tilt your head slightly backward. Start breathing slowly through your mouth. At the same time press down firmly at the top of the canister to release medicine. Continue to breathe in steadily & deeply.



5. Remove the inhaler from your mouth & hold your breath for 10 seconds or as long as it is comfortable. Then breathe out gently. If you take a second inhalation, you should wait for at least one minute before repeating steps 3 & 4.



6. After use, replace the mouthpiece cap.

Important



Do not rush steps 4 and 5. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of the mirror for the first few times. If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 2. This escaping mist indicates incorrect technique.

How to clean your inhaler?



1. Remove the metal canister from the actuator (plastic casing) of the inhaler & remove the mouthpiece cap.

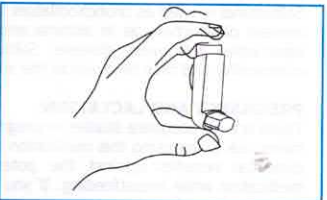


2. Immerse the actuator (plastic casing) & the mouthpiece cap in warm water for few minutes and then rinse them under running water. But do not put the metal canister into water.

3. Leave actuator & mouthpiece cap to dry in warm place, avoid excessive heat.

4. Replace the canister and the mouthpiece cap correctly.

Your inhaler should be cleaned at least once a week.



Tips for children

Children & others who have weaker hands may have difficulty pressing down on the top of the canister with just one hand. They can use both hands to make their inhaler work.