

IPRATROPIUM BROMIDE SALBUTAMOL

Ipralin
20 mcg/100 mcg per
Actuation Suspension
Metered Dose Inhaler
Bronchodilator



Formulation:

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

Product Description:

Aluminium canister 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.

Pharmacology:

Ipratropium bromide:
Ipratropium bromide is a quaternary ammonium compound with anticholinergic (parasympatholytic) properties. Similar to atropine, it is a non-selective competitive antagonist of muscarinic receptors present in airways and other organs. Ipratropium bromide relaxes smooth muscles of bronchi and bronchioles by blocking acetylcholine-induced stimulation of guanyl cyclase, thus reducing formation of cyclic guanosine monophosphate (cGMP), a mediator of bronchoconstriction. Ipratropium generally exhibits greater antimuscarinic activity of bronchial smooth muscle than on secretory (e.g. salivary, gastric) glands. Ipratropium bromide is a potent bronchodilator, particularly in large bronchial airways; however some evidence suggest that it also hits bronchodilator activity in small airways. Bronchodilation results from relaxation of smooth muscles of the bronchial tree. The extent of bronchodilation produced by ipratropium appears to be determined by the level of cholinergic parasympathetic bronchomotor tone and by inhibition of bronchoconstriction resulting from neural reflex activation of cholinergic pathways.

Salbutamol:

Salbutamol stimulates adenylyl cyclase, the enzyme which catalyzes the formation of cyclic-3', 5'-adenosine monophosphate (cAMP) from adenosine triphosphate (ATP). The cAMP thus formed mediates the cellular response eg. bronchial smooth muscle relaxation.

Ipratropium bromide-salbutamol fixed-dose combination (FDC) maximizes the response to treatment in patients with bronchial asthma and chronic obstructive pulmonary disease (COPD) by increasing bronchodilation through 2 distinctly different mechanism i.e., anticholinergic (parasympathomimetic) and Beta 2 Antagonist (sympathomimetic) effects. Simultaneous administration of both an anti-cholinergic (Ipratropium bromide) and a Beta 2-Sympathomimetic (salbutamol sulfate) produces a greater bronchodilator effect than when other drug is used alone.

Indications:

Ipratropium Bromide + Salbutamol Sulfate (Ipralin) Inhaler 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 & administration:

Adults and children ≥ 12 years: Two (2) actuations every 6 hours.
Patients may have additional inhalations as required but should not exceed twelve (12) actuations in 24 hours.

Contraindications:

Hypersensitivity to soya lecithin or related food products eg. soybeans or peanuts and any components of the drug product, atropine and its derivatives. Hypertrophic obstructive cardiomyopathy or tachyarrhythmia. Also contraindicated in patients hypersensitive to any component of the drug product or to atropine or its derivatives.

Warnings:

Paradoxical Bronchospasm

Ipratropium Bromide + Salbutamol Sulfate (Ipralin) can produce paradoxical bronchospasm that can be life-threatening. If it occurs, the preparation should be discontinued immediately and alternative therapy may be instituted.

Cardiovascular Effect

The salbutamol Sulfate contained in Ipratropium Bromide + Salbutamol Sulfate (Ipralin) inhaler, like other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure and/or symptoms. Although such effects are uncommon after administration of Bromide + Salbutamol Sulfate (Ipralin) Inhaler at recommended doses, if they occur, discontinuation of the drug may be indicated. In addition, beta-adrenergic agents have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. Therefore, Ipratropium Bromide + Salbutamol Sulfate (Ipralin) inhaler should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias and hypertension.

Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs, in patients with asthma. The exact cause of death is unknown, but cardiac arrest following an unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of ipratropium bromide or salbutamol sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema.

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:

Ipratropium bromide containing inhaler should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction.

Salbutamol Sulfate containing inhaler 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. Combination of Ipratropium and Salbutamol Inhaler has not been studied in patients with hepatic or renal insufficiency. It should be used with caution in those patient populations.

Side-effects:

Headache, pain, influenza, bronchitis, dyspnea, coughing, respiratory disorders, pneumonia, upper respiratory tract infection, pharyngitis, sinusitis, rhinitis have been reported. Additional adverse reactions reported include 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.

High risk groups:

Use in pregnancy:

Pregnancy Category C. There are no adequate and well-controlled studies of ipratropium bromide and salbutamol sulfate inhaler, ipratropium bromide or salbutamol sulfate, in pregnant women. Ipratropium Bromide + Salbutamol Sulfate (Ipralin) Inhaler should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation:

It is not known whether the components of Ipratropium Bromide + Salbutamol Sulfate (Ipralin) Inhaler are excreted in human milk. Ipratropium Bromide + Salbutamol Sulfate (Ipralin) Inhaler should not be used by breastfeeding mothers, unless the expected benefit is thought to outweigh the risks.

Use in children:

Safety and effectiveness in the pediatric population have not been established.

Drug interactions:

Ipratropium bromide and salbutamol sulfate inhaler has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, and oral and inhaled steroids, commonly used in the treatment of chronic obstructive pulmonary disease.

With the exception of salbutamol, there are no formal studies fully evaluating the interaction effects of ipratropium bromide and salbutamol sulfate inhaler and these drugs with respect to effectiveness.

Anticholinergic agents: Although ipratropium bromide is minimally absorbed into the systemic circulation, there is some potential for an additive interaction with concomitantly used anticholinergic medications. Caution is therefore advised in the co-administration of ipratropium bromide and salbutamol sulfate inhaler with other anticholinergic-containing drugs.

Beta-adrenergic agents: Caution is advised in the co-administration of ipratropium bromide and salbutamol sulfate inhaler and other sympathomimetic agents due to the increased risk of adverse cardiovascular effects. Beta-receptor blocking agents and salbutamol inhibit the effect of each other. Beta-receptor blocking agents should be used with caution in patients with hyperreactive airways.

Diuretics: The ECG changes and/or hypokalemia which may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the co-administration of beta-agonist-containing drugs, such as ipratropium bromide and salbutamol sulfate inhaler, with non-potassium sparing diuretics.

Monoamine oxidase inhibitors or tricyclic antidepressants:

Ipratropium bromide and salbutamol sulfate inhaler should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants or within two weeks of discontinuation of such agents because the action of salbutamol on the cardiovascular system may be potentiated.

CAUTION:

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

STORAGE CONDITIONS:

Store at temperatures not exceeding 30°C. Exposure to temperature above 49°C (120°F) may cause bursting. Do not break, puncture or burn the canister even when apparently empty.

AVAILABILITY:

Aluminium Canister with metered valve and actuator x 200 actuations (Box of 1's)

FDA Registration No. : DRP-12203

Date of First Authorization : 02 July 2022

Date of Revision of Package Insert : 30 January 2023

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

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

Important information for the patients

IPRATROPIUM BROMIDE SALBUTAMOL

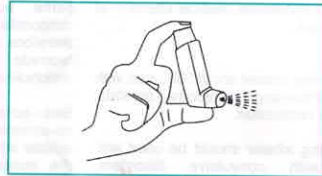
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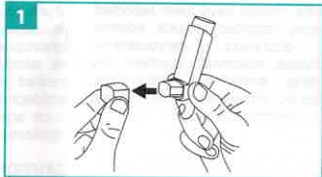
How to use your inhaler correctly?

Test your inhaler

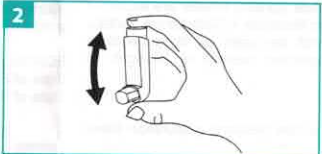


Before using your Inhaler for the first time, or if it has not been used for a week or more, shake it well and then "test fire" it, i.e. release one puff into the air.

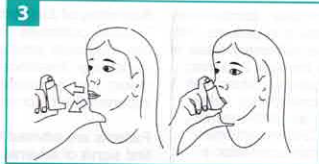
Using your inhaler



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



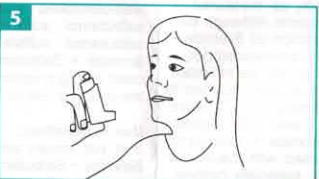
2. Hold canister as illustrated in figure. Shake the canister vigorously for at least 10 seconds.



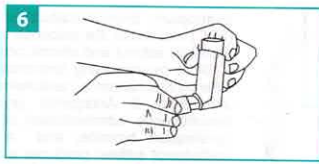
3. Breathe out gently as you can and immediately place the mouthpiece in your mouth between your teeth. Do not bite it.



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

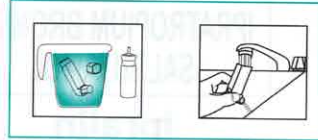


Do not rush steps 4 and 5. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of the mirror for the first few times. If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 2. This escaping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

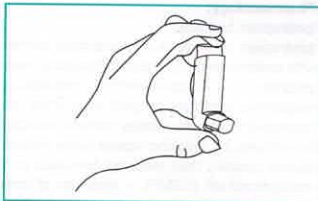


2. Immerse the actuator (plastic casing) & the mouthpiece cap in warm water for few minutes and then rinse them under running water. But do not put the metal canister into water.

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.

Parts of an inhaler

