Export Philippines
Date: 22.02.2022

240mm

171mm

IPRATROPIUM BROMIDE SALBUTAMOL

Ipralin

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

Rx CFC Free

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 quarternary ammonium compound with anticholinergic (parasympatholytic) properties. Similar to atropine, it is a non-selective competetive 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 reflux activation of cholinergic pathways.

Salbutamol:
Salbutamol stimulates adenyl 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 ie., anticholinergic (parasympthomimetic) and Beta 2 Antagonist (sympathomimethic) effects. Simultaneous administration of both an anti-cholinergic (Ipratropium bromide) and a Beta 2-Sympathomimetic (salbutamol sulfate) produces a greaterbronchodilator 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 chidlren ≥ 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 temperature 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. : DR-XY45781
Date of First Authorization : 30 January 2022
Date of Revision of Package Insert : 21 Fubruary 2022

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

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

20004391/01