Ipralin® Nebuliser Solution

Ipratropium Bromide 0.5 mg &
Salbutamol 2.5 mg

COMPOSITION

Ipralin® Nebuliser Solution: Each 3 ml ampoule contains Ipratropium Bromide BP 0.5 mg and Salbutamol Sulphate BP 3 mg equivalent to 2.5 mg Salbutamol.

PHARMACOLOGY

Ipralin® Nebuliser Solution contains Ipratropium Bromide and Salbutamol Sulphate. Ipratropium Bromide is an anticholinergic (parasympatholytic) agent, which inhibits vagally-mediated reflexes by antagonizing the action of acetylcholine, released from the vagus nerve. Anticholinergics prevent the increase in intracellular concentration of cyclic guanosine monophosphate (cGMP), which are caused by the interaction of acetylcholine with the muscarinic receptors on bronchial smooth muscle. This opens bronchi and causes bronchodilation. Salbutamol is a selective beta$_2$-adrenoceptor agonist. At therapeutic doses, it acts on the beta$_2$-adrenoceptors of bronchial smooth muscle, with little or no action on the beta$_1$-adrenoceptors of cardiac muscle. Salbutamol provides short acting bronchodilatation with a fast onset of action in reversible airways obstruction.

INDICATIONS

Ipralin® Nebuliser Solution 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

1 single dose unit, three or four times a day for adults (including the elderly). Children use & dose must be determined by doctor.

SIDE EFFECTS

Headache, pain, influenza, bronchitis, dyspnea, coughing, respiratory disorders, pneumonia, upper respiratory tract infection, pharyngitis, sinusitis, rhinitis has 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.

CONTRAINDICATION

Ipralin® Nebuliser Solution is contraindicated in patients with cardiac tachyarrhythmias and hypertrophic obstructive cardiomyopathy & in patients with a history of hypersensitivity to any of its components or to atropine or its derivatives.

WARNINGS

Paradoxical Bronchospasm

Ipralin® Nebuliser Solution 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 Sulphate contained in **Ipralin®** Nebuliser Solution, 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 **Ipralin®** Nebuliser Solution 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, **Ipralin®** Nebuliser Solution 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 Sulphate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis and oropharyngeal edema.

PRECAUTIONS

Ipratropium Bromide containing **Ipralin®** nebuliser solution should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Salbutamol Sulphate containing **Ipralin®** nebuliser solution should be used with caution in patients with convulsive disorders, hyperthyroidism or diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines.

USE IN SPECIAL GROUPS

Use in pregnancy

The safety of **Ipralin®** Nebuliser Solution in pregnancy has not been established. There are no adequate and well-controlled studies of **Ipralin®** Nebuliser Solution in pregnant women. **Ipralin®** Nebuliser Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the unborn child.

Use in lactation

Salbutamol is probably excreted in breast milk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate. No specific studies have been conducted on the excretion of Ipratropium Bromide in breast milk. However, caution should be exercised when **Ipralin®** Nebuliser Solution is administered to nursing mothers.

Use in elderly patients

Elderly patients can use **Ipralin®** Nebuliser Solution at the recommended dose.

DRUG INTERACTIONS

The concurrent administration of other beta-mimetics, systemically absorbed anticholinergics and xanthine derivatives may increase the side effects.

Beta-agonist induced hypokalaemia may be increased by concomitant treatment with xanthine derivatives, glucocorticosteroids and diuretics. This should be taken into account particularly in patients with severe airway obstruction.

Hypokalaemia may result in an increased susceptibility to arrhythmias in patients receiving digoxin. It is recommended that serum potassium levels be monitored in such situations.

A potentially serious reduction in bronchodilator effect may occur during concurrent administration of beta-blockers.

Beta-adrenergic agonists should be administered with caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, since the action of beta-adrenergic agonists may be enhanced.

Inhalation of halogenated hydrocarbon anesthetics such as halothane, trichloroethylene and enflurane may increase the susceptibility to the cardiovascular effects of beta-agonists.

OVERDOSE

The expected symptoms with salbutamol overdosage are those of excessive beta-adrenergic stimulation, such as: tachycardia, palpitations, tremor, cardiac arrhythmia, hypokalemia, hypertension, hypotension, widening of pulse pressure, anginal pain, flushing and in extreme cases, sudden death. In such case treatment with **Ipralin®** Nebuliser Solution should be discontinued.

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

PACKING

Ipralin® Nebuliser Solution: Each box contains 10 ampoules in Alu-PVC blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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