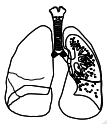

Iprex®

Ipratropium

Anticholinergic bronchodilator

COMPOSITION

Iprex® inhaler : Each puff delivers 20 µg of Ipratropium Bromide BP. Each canister of Iprex® inhaler contains 4 mg of Ipratropium Bromide BP.

INDICATION

- As bronchodilator in treatment of chronic reversible airway obstruction as in asthma and Chronic Obstructive Pulmonary Disease (COPD) including chronic bronchitis and emphysema.
- Treatment of acute reversible airways obstruction.

DOSAGE AND ADMINISTRATION

For inhalation only.

Adults: The usual dose is 1-2 puffs (20 µg/puff) three or four times daily. Single dose up to 80 ug (4 puffs) may be required to obtain maximum benefit during early treatment.

Patients may take additional inhalations as required: however, the total number of inhalations should not exceed 12 puffs in 24 hours.

Children: 6-12 years: Usually 1-2 puffs two to three times dally.

Bellow 6 years : The usual dose is 1 puff (20 µg) three times daily.

In order to ensure that the inhaler is used correctly, administration should be supervised by an adult.

No specific information on the use of the product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

CONTRAINDICATION AND PRECAUTION

Known hypersensitivity to ipratropium bromide, Atropine or its derivative. Also contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soyabean, lecithin and peanut.

Patients should be advised that temporary blurring of vision, precipitation or worsening of narrow angle glaucoma or eye pain may result if the aerosol is sprayed into the eyes.

If recommended dosage does not provide relief or symptoms become worse, patients should seek immediate medical attention. While taking ipratropium bromide inhalation aerosol, other inhaled drugs should not be used unless prescribed.

Ipratropium bromide inhalation aerosol is not indicated for the initial treatment of acute episodes of bronchospasm where rapid response is required. Drugs with faster onset may be preferable as initial therapy in this situation. Immediate hypersensitivity reactions may occur after administration of ipratropium bromide, as demonstrated by rare cases of urticaria, angio-oedema, rash, bronchospasm and oropharyngeal oedema.

SIDE EFFECT

Idiosyncratic reactions to Ipratropium bromide are rare. Severe adverse effects due to inhibition of muscarinic receptors and ganglion blockade are theoretically possible but unlikely with the metered-dose aerosol.

Regular use of ipratropium can lead to a dry mouth through inhibition of salivary flow.

Other most common adverse reactions reported are - dryness of the oropharynx (5%); cough, exacerbation of symptoms, & imitation from aerosol (3%); headache (2%); nausea, dizziness, blurred vision/difficulty in accommodation & drying of secretions (1%).

Less frequently reported adverse reactions include tachycardia, nervousness, paresthesias, drowsiness, co-ordination difficulty, itching, flushing, alopecia, constipation, tremor & mucosal ulceration.

Case of precipitation or worsening of narrow-angle glaucoma, acute eye pain & hypotension also have been reported.

Allergic-type reactions such as skin rash, angio-oedema of tongue, lips & face, urticaria (including giant urticaria), laryngospasm and anaphylactic reaction have been also reported; with positive rechallenge in some cases.

Ipratropium bromide dose not produce adverse effects on mucociliary clearance, in contrast to atropine and other muscarinic antagonists. There is no evidence that in the therapeutic does range ipratropium bromide has any adverse effect on bronchial secretion.

DRUG INTERACTION

Ipratropium bromide has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, steroids and cromolyn sodium, commonly used in treatment of COPD, without any adverse drug reactions, there are no studies fully evaluating the interaction effects of Ipratropium bromide and these drugs in respect to effectiveness.

OVERDOSAGE

Acute overdosage by inhalation is unlikely since ipratropium bromide is not well absorbed systematically after administration as aerosol. Inhaled dosage of 5 mg of ipratropium bromide produce an increase in heart rate and palpitation. Single doses of ipratropium bromide 30 mg by mouth caused anticholinergic side effects but which were not considered severe enough to require specific reversal.

Legal Category

To be dispensed only by the prescription of registered physicians.

STORAGE CONDITION

The inhaler should be stored in a dry and cool place. Protected from direct sunlight and heat. Keep away from eyes. Keep out of reach of children. The canister should not be broken, punctured or burnt, even when apparently empty.

HOW SUPPLIED

Iprex® inhaler : Each canister contains Ipratropium Bromide BP 4 mg (minimum 200 puffs). Each puff delivers Ipratropium Bromide BP 20 µg.