Iprex®

HFA Inhaler
200 puffs

Ipratropium Bromide BP

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

Indication
As bronchodilator in the treatment of chronic reversible airway obstruction as in asthma and chronic obstructive pulmonary disease 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 gm/spray) three or four times daily. Single dose upto 80 gm (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 in 24 hours.

Children:
6-12 years –Usually 1-2 puffs two to three times daily.
Below 6 years - The usual dose is 1 puff (20 gm) 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.

Contraindications
Known hypersensitivity to Ipratropium, Atropine or its derivative. Also contraindicated in patients with a history of hypersensitivity to soya lecithin or relate food products such as soybean, lecithin and peanut.

Precautions
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 inhalation aerosol, other inhaled drugs should not be used unless prescribed.

Ipratropium 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 Effects
Potentially life threatening effects – 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.
Severe/Irreversible adverse effects – No effects of this kind is reported.
Symptomatic adverse effects – Regular use of Ipratropium can lead to a dry mouth through inhibition of salivary flow.

Observed during clinical practice – The most common adverse reactions reported are -- dryness of the oropharynx (5%); cough, exacerbation of symptoms, & irritation 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, coordination difficulty, itching, hives, flushing, alopecia, constipation, tremor & mucosal ulceration. Case of precipitation or worsening of narrow-angle glaucoma, acute eye pain & hypotension 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 does not produce adverse effects on mucocilliary clearance, in contrast to atropine and other muscarinic antagonists. There is no evidence that in the therapeutic dose range Ipratropium has any adverse effect on bronchial secretion.

Drug Interactions
Ipratropium has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, steroids and cromolyn sodium, commonly used in the treatment of chronic obstructive pulmonary disease, without adverse drug reactions. There are no studies fully evaluating the interaction effects of Ipratropium and these drugs with respect to effectiveness.

Overdosage
Acute overdosage by inhalation is unlikely since Ipratropium bromide is not well absorbed systematically after aerosol administration. Inhaled dosage of 5 mg 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.

How supplied
Each puff delivers Ipratropium bromide BP 20 mg, 200 puffs.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH