Iprex® Respirator Solution

Ipratropium bromide solution for oral inhalation (with the aid of a nebulizer) is a synthetic quaternary anticholinergic parasympatholytic ammonium compound chemically related to atropine which appears to inhibit vagally-mediated reflexes by antagonizing the action of acetylcholine, the transmitter agent released by the vagus nerve. It is a competitive antagonist at the muscarinic acetylcholine receptors. The bronchodilation following inhalation of Ipratropium is primarily a local, site-specific effect, not a systemic one.

Composition:

Each amber glass phial providing a clear, colorless isotonic solution of Ipratropium bromide 0.025% w/v (250 mcg/ml) for administration by inhalation with the aid of nebulizer.

Indication:

1. As a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.
2. Can be used in chronic treatment of patients with reversible airway obstruction who fail to respond to nebulized beta-sympathomimetic agents.

Dosage & Administration:

Adults (including elderly):
The usual dosage of Ipratropium bromide inhalation solution is 100-500 mcg administered three to four times a day by oral nebulization, with doses six to eight hours apart. It can be given up to 4-hrly by nebulization either alone or as an adjuvant in acute reversible airway obstruction. It can be mixed in the nebulizer with Salbutamol if used within an hour.

Children:
The dose recommended in asthmatic children is 100-500 mcg up to three times a day via nebulizer for the treatment of acute severe asthma.
1 month-3 year: 62.5 - 250 mcg up to three times daily.
3-14 years: 100 - 250 mcg three times daily.

Safety and effectiveness in the population below the age of 12 years have not been established.

Dilution of solution is adjusted according to equipment and length of administration. If dilution is necessary, only sterile 0.9% sodium chloride should be used. As paradoxical bronchospasm has occurred, first dose should be inhaled under strict medical supervision.

Contra-indication:

Ipratropium is contraindicated in patients with known hypersensitivity to Ipratropium, Atropine or its derivative.

Adverse reactions:

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 – Anticholinergic side effects are unlikely at therapeutic doses, but some patients may complain of a dry mouth. The most common adverse reactions reported are – Tachycardia, palpitation, eye pain, urinary retention, urinary tract infection, and urticaria.

Headache, mouth dryness and aggravation of COPD symptoms were more common with >2000 mcg/day. Cases of precipitation or worsening of narrow-angle glaucoma and acute eye pain has been reported. Allergic-type reactions such as skin rash, angio-oedema of tongue, lips & face; urticaria (including giant urticaria), laryngospasm & anaphylactic reaction have been also reported.

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.

Overdosage:

Acute systemic overdosage by inhalation is unlikely since Ipratropium bromide is not well absorbed systematically after inhalation at up to four-fold the recommended dose, or after oral administration at up to fort-fold the recommended dosage. Inhaled dosage of 5 mg produced 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. No action other than medical observation should be necessary.

Drug interactions:

Ipratropium bromide 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.

Precaution & warning:

Ipratropium should be used with precaution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder neck obstruction. Patients should be advised that temporary blurring of vision precipitation or worsening of narrow-angle glaucoma or eye pain might result if the solution comes into direct contact with eyes. Use of nebulizer with mouthpiece rather than facemask may be preferable, to reduce the likelihood of the nebulizer solution reaching the eyes. Patients should be advised that Ipratropium nebulizer solution can be mixed in the nebulizer with Salbutamol if used within one hour. Patients should be reminded that Ipratropium inhalation solution should be used consistently as prescribed throughout the course of therapy.

The use of Ipratropium bromide inhalation solution as a single agent for the relief of bronchospasm in acute COPD exacerbation has not been adequately studied. Drugs with faster onset of action may be preferable as initial therapy in this situation. Combination of Ipratropium and Beta agonists has not been shown to be more effective then either drug alone in reversing the bronchospasm associated with acute COPD exacerbations. Immediate hypersensitivity

reactions may occur after administration of Ipratropium bromide, as demonstrated by rare cases of urticaria, angio-oedema, rash, bronchospasm and oropharyngeal edema.

Failure to respond by improvement in lung function and/or blood gas in patients treated with Ipratropium alone should be treated with the addition of treatment with inhaled beta-sympathomometic agents.

Use in pregnancy & lactation:

Oral reproduction studies performed in mice, rats and rabbits at doses of 10, 100 and 125 mg/kg respectively, and inhalation reproduction studies in mice, rats and rabbits at doses of 1.5 and 1.8 mg/kg (or approximately 38 and 45 times the recommended human daily dose) respectively, have demonstrated no evidence of teratogenic effects because of Ipratropium. However, no adequate or well-controlled studies have been conducted in pregnant women. As animal reproduction studies are not always predictive of human response, Ipratropium should be used during pregnancy only if clearly needed.

It is not known whether Ipratropium is excreted in human milk. Although lipid-insoluble quaternary bases pass into breast milk, it is unlikely that Ipratropium would reach the infant to a significant extent, especially when taken by inhalation since Ipratropium is not well absorbed systematically after inhalation or oral administration. However, because many drugs are excreted in human milk, caution should be exercised when administered to a nursing mother.

Warning:

The contents should be used with in one month after the bottle is opened.

Storage condition:

Store below 25^0 C.
Protect from light.
Keep the medicine out of the reach of children.

How supplied:

Phial containing 20 ml. solution of 0.025% w/v of Ipratropium bromide (250 mcg/ml.).

Manufactured by:
SQUARE PHARMACEUTICALS LTD.
PABNA, BANGLADESH