EASEHALE RESPULES 0.025%  

INTERACTIONS WITH OTHER MEDICINES
This medicine should not be used with IPRATROPIUM BROMIDE inhalation with other anticholinergic drugs has not been studied. Therefore, the chronic co-administration of IPRATROPIUM BROMIDE with other anticholinergic drugs is not recommended. ballistic relaxation of the bronchi without decreasing the bronchial smooth muscle. IPRATROPIUM BROMIDE is a synthetic tertiary amine that is readily ionized to the ipratropium ion. Hydrochloric acid is added to achieve a pH of about 3.5 which is suitable for inhalation.

PHARMACOKINETICS
Carcinogenicity

Kinetic parameters describing the disposition of IPRATROPIUM BROMIDE were calculated from plasma concentrations after intravenous administration. A rapid biphasic decline in plasma concentrations is observed. The volume of distribution (Vz) is 338 L (approximately 4.6 L/kg). The half-life of the terminal elimination phase is about 1.6 hours. The drug is less than 20% bound to plasma proteins. The ipratropium ion does not cross the blood-brain barrier. Therefore, the volume of distribution is reduced in patients with diminished cardiac reserve; chronic obstructive pulmonary disease; renal impairment; liver insufficiency and congestive heart failure.

Distribution
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Metabolism
The total clearance of the drug is 2.3 ± 0.7 L/min. The major portion, approximately 60% of the systemically available dose, is eliminated by metabolic degradation, probably in the liver. The major urinary metabolites bind poorly to the mouse anticholinergic receptor and are inactive. In the absence of atropine or its derivatives (such as the active substance ipratropium bromide), or to any of the other ingredients of IPRATROPIUM BROMIDE (Respules are listed under DESCRIPTION).

PRECAUTIONS
Hyperactivity

Hypersensitivity

Immediate hypersensitivity reactions may occur after administration of IPRATROPIUM BROMIDE as demonstrated by skin reactions. Intolerance to excipients and side-effects have also been noted.

Paradoxical Bronchospasm

An increased or paradoxical bronchoconstriction may result in bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, IPRATROPIUM BROMIDE should be discontinued immediately and medical attention sought.

Anticholinergic Effects

Like other drugs with anticholinergic activity, IPRATROPIUM BROMIDE should be avoided or used with caution in patients where atropine-like effects may precipitate or exacerbate a pre-existing clinical condition. Patients at particular risk are those with glaucoma, prostatic hypertrophy, peptic ulcer disease, or hyperactive bladder. In these patients, atropine-like effects may be manifest as pupillary dilation, mydriasis, blurring of vision, increased intraocular pressure, decreased accommodation, difficulty in micturition, and constipation. Anticholinergics may cause dryness of the mouth, which may be more pronounced in patients with diminished salivary output. Anticholinergic effects may also occur in any patient treated with IPRATROPIUM BROMIDE, although such effects are uncommon. In the event of excess salivation, patients should be instructed to use a dry mouth rinse. When necessary, a cholinergic agent such as pilocarpine may be used in an attempt to improve the condition.

CONTRAINDICATIONS

Use in Patients with a History of Atropine-like or Anticholinergic Effects (such as the active substance ipratropium bromide), or to any of the other ingredients of IPRATROPIUM BROMIDE (Respules are listed under DESCRIPTION).

IPRATROPIUM BROMIDE can be administered combined with a short-acting β2-agonist. Thus, patients must be instructed in the correct administration of IPRATROPIUM BROMIDE inhalation solutions, no serious anticholinergic symptoms are to be expected. If your doctor has told you that your medicine needs to be diluted, you will be given sterile sodium chloride 0.9% solution. Your doctor will tell you how to do this. If you are not sure how to do this, or if you are in doubt, consult a doctor or pharmacist. If you have also been prescribed a medicine called a ‘short-acting beta2-agonist nebuliser solution’ such as Albuterol or Turbohaler, it is important to keep your nebuliser clean.

DOSAGE AND ADMINISTRATION

DOSAGE can be administered via a range of commercially available nebulising devices. Where low volume is available, solutions are best administered at a flow rate of 4.0 to 6.0 per minute. Dosage is dependent on the condition being treated and the response of the patient as determined by the attendant medical practitioner. In cases of moderate bronchospasm or with assisted ventilation, a dose in the lower range of 261 µg/20 drops from the dropper insert in the multidose bottle equal approximately 261 µg of IPRATROPIUM BROMIDE should be administered simultaneously. IPRATROPIUM BROMIDE and disodium cromoglycate inhalation solutions should not be mixed in the same nebuliser. The following adverse reactions were reported in the clinical studies at the following frequency: very common (≥1/10), common (≤1/10, <1/100), uncommon (≤1/100, <1/1000), rare (≤1/1000, <1/10,000), very rare (≤1/10,000).

Sedation

Sedative effects such as drowsiness and somnolence may occur after administration. In excretion balance studies, after intravenous administration of a radioactive dose, less than 10% of the drug-related radioactivity (including parent compound and all 3 metabolites), are excreted via the biliary-faecal route. The experimental renal clearance of 0.9 L/min. After oral dosing less than 1% of the dose is renally excreted. IPRATROPIUM BROMIDE has no known effects on the ability to drive or operate machinery.

Adverse Effects

In excretion balance studies, after intravenous administration of a radioactive dose, less than 10% of the drug-related radioactivity (including parent compound and all 3 metabolites), are excreted via the biliary-faecal route. The experimental renal clearance of 0.9 L/min. After oral dosing less than 1% of the dose is renally excreted. IPRATROPIUM BROMIDE has no known effects on the ability to drive or operate machinery.

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