

IPRATROPIUM (Inhalation-Local)

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Bronchitis, chronic (treatment) or

Emphysema, pulmonary (treatment) or

Pulmonary disease, chronic obstructive, other (treatment)³Ipratropium is indicated for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and pulmonary emphysema. Regular use of ipratropium results in at least as great an increase in airflow as that with use of other bronchodilators and fewer adverse effects. If additional bronchodilation is needed in these patients, an adrenergic bronchodilator may be used as an adjunct to ipratropium. 10, 14, 15, 16, 30, 40, 43, 44, 45, 46

[Ipratropium is indicated as an adjunct to adrenergic bronchodilators⁹ for treatment of acute exacerbations of chronic obstructive pulmonary disease 3, 9, 19, 40, 46.]

[Asthma (treatment adjunct)]⁴Ipratropium is used as an adjunct to anti-inflammatory therapy or bronchodilators to prevent * exacerbations of asthma in patients who respond poorly to therapy³⁶ or as an alternative to other bronchodilators in patients who develop significant side effects with these medications 12, 14, 18.

Ipratropium is used as an adjunct to adrenergic bronchodilators for the treatment of acute exacerbations of asthma 4, 32, 39.

It is not used alone because it has a relatively slower onset of action and time to peak effect as compared with adrenergic bronchodilators 7, 36.

Precautions to Consider

Cross-sensitivity and/or related problems

Patients sensitive to belladonna alkaloids may be sensitive to ipratropium also, since ipratropium is chemically related to atropine 1.

Although rare, allergic reactions to ipratropium metered-dose inhaler have been reported; however, the causative component has not been identified. Therefore, patients allergic to soybean protein or other legumes, such as peanuts, may be allergic to soya lecithin contained in the metered-dose inhaler as a suspending agent. 2, 33, 35, 37

Carcinogenicity/Tumorigenicity

Two-year carcinogenicity studies in mice and rats have shown that ipratropium, at oral doses up to 1250 times the maximum recommended human daily dose, has no carcinogenic potential 2.

Also, studies in mice and rats have shown that ipratropium, at oral doses up to 6 mg per kg of body weight (mg/kg), does not have a carcinogenic or tumorigenic effect 1.

Mutagenicity

Various studies in mice and hamsters have shown that ipratropium is not mutagenic 1, 2.

Pregnancy/Reproduction

Fertility³ Although studies in male and female rats have shown that ipratropium, at oral doses up to approximately 10,000 times the maximum recommended human daily dose, does not affect fertility, ipratropium has been shown to increase resorption and decrease conception rates when the medication was administered at doses above 18,000 times the maximum recommended human daily dose 2.

Pregnancy³ Although adequate and well-controlled studies in humans have not been done, no increased risk of congenital malformation has been reported.

Reproduction studies with ipratropium in mice, rats, and rabbits given oral doses of 10, 100, and 125 mg per kg of body weight (mg/kg), respectively, and in rats and rabbits given inhalation doses of 1.5 and 1.8 mg/kg (or approximately 38 and 45 times the recommended human daily dose), respectively, have shown no evidence of teratogenic effects 1.

FDA Pregnancy Category B 1.

Breast-feeding

It is not known whether ipratropium is distributed into breast milk. However, problems in humans have not been documented. Although lipid-insoluble quaternary bases, such as ipratropium, are distributed into breast milk, it is unlikely that inhaled ipratropium would reach significant concentrations in maternal serum, and the concentration in breast milk would probably be undetectable. 1

Pediatrics

Appropriate studies performed to date have not demonstrated pediatrics-specific problems that would limit the usefulness of ipratropium in children 42.

Geriatrics

Studies performed to date on patients over 65 years of age have not demonstrated geriatrics-specific problems that would limit the usefulness of ipratropium inhalation in the elderly 15, 19.