Rynaspray®

Ipratropium bromide BP 21 mcg/spray

Composition: Ipratropium bromide nasal spray is an aqueous isotonic, pH-adjusted (pH 4.0 - 5.0) solution for nasal administration. It is a metered dose, manual pump spray which delivers 21 mcg Ipratropium bromide BP per spray.

Pharmacology: Ipratropium bromide is an anticholinergic agent that inhibits vagally-mediated reflexes by antagonizing the action of acetylcholine at the cholinergic receptor. In humans, Ipratropium bromide has antisecretory properties and when applied locally, inhibits secretions from the serous and seromucous glands lining the nasal mucosa. Ipratropium bromide is a quaternary amine that minimally crosses the nasal and gastrointestinal membrane and the blood-brain barrier, resulting in a reduction of the systemic anticholinergic effects (e.g. neuroleptic, ophthalmic, cardiovascular, and gastrointestinal effects) that are seen with tertiary anticholinergic amines.

Indications and uses: Ipratropium bromide nasal spray is indicated for the treatment and management of perennial rhinitis, allergic rhinitis and vasomotor rhinitis when characterized by watery rhinorrhoea.
Ipratropium bromide nasal spray is also indicated for the symptomatic relief of rhinorrhoea associated with the common cold. Ipratropium bromide nasal spray does not relieve nasal congestion, sneezing, or postnasal drip associated with allergic or non-allergic perennial rhinitis.

Dosage and administration: *For the treatment and management of perennial rhinitis, allergic rhinitis and vasomotor rhinitis when characterized by watery rhinorrhoea*: 2 sprays into each nostril 2-4 times daily in adults and children age 5 years and older.

For the symptomatic relief of rhinorrhoea associated with the common cold:
The recommended dose is 2 sprays in to each nostril 2-4 times daily in adults and children age 5 years and older.

The safety and effectiveness of Ipratropium bromide nasal spray in pediatric patients under 5 years of age have not been established. The safety and effectiveness of Ipratropium bromide nasal spray beyond 3 weeks in patients with allergic rhinitis and 4 days in patients with the common cold have not been established.

Initial pump priming requires seven sprays of the pump. If used regularly as recommended, no further priming is required. If not used more than 24 hours, the pump will require 2 sprays, or if not used for more than seven days, the pump will require 7 sprays.

Contraindication and warnings: Known hypersensitivity to atropine or its derivatives, or to any of the ingredients of Ipratropium bromide nasal spray (sodium chloride, benzalkonium chloride, disodium edetate dihydrate). Immediate hypersensitivity reactions may occur after administration of Ipratropium bromide, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema.

Precautions: Ipratropium bromide nasal spray should be used with caution in patients predisposed to narrow-angle glaucoma, or with prostatic hyperplasia or bladder neck obstruction. Patients with cystic fibrosis may be more prone to gastro-intestinal motility disturbances.

Side effects: The most frequent local undesirable effects of Ipratropium bromide nasal spray are nasal reactions including epistaxis, dryness of the nose and nasal irritation. Headache, nausea and local irritation (e.g. burning sensation) may occur as non-specific reactions in association with use of Ipratropium bromide nasal spray. Potential systemic anticholinergic effects are dry mouth and dry throat. Ocular side effects, increase of heart rate and palpitations, urinary retention and gastrointestinal motility disturbances have been reported in isolated patients in association with use of Ipratropium bromide either intranasally or after oral inhalation. Allergic-type reactions such as skin rash, angio-oedema of tongue, lips and face, urticaria, laryngospasm and anaphylactic reactions may occur.

Drug interaction: No controlled clinical trials were conducted to investigate drug-drug interactions. Ipratropium bromide nasal spray is minimally absorbed into the systemic circulation; nonetheless, there is some potential for additive interaction with other concomitantly administered anti-cholinergic medications, including Ipratropium bromide containing aerosols for oral inhalation.

Use in pregnancy: The safety of Ipratropium bromide nasal spray during pregnancy has not been established. The benefits of using this spray during a confirmed or suspected pregnancy must be weighed against possible hazards to the unborn child. Preclinical studies showed no embryotoxic or teratogenic effects following inhalation at doses considerably higher than those recommended in man.

Use in nursing mother: It is not known whether Ipratropium bromide is excreted into human milk. Although lipid-insoluble quaternary cations pass into breast milk, the minimal systemic absorption makes it unlikely that Ipratropium bromide would reach the infant in an amount sufficient to cause a clinical effect. However, because many drugs are excreted into human milk, caution should be exercised when Ipratropium bromide nasal spray is administered to a nursing mother.

Use in children: The safety and effectiveness of Ipratropium bromide nasal spray in patients under 5 years of age have not been established.

Storage: Store in a safe place out of the reach of children. Store below 30°C. Avoid freezing. Do not spray in the eyes.

How supplied: Amber bottle containing Ipratropium bromide aqueous solution adequate for 120 metered doses.

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