ATTENTION PHARMACIST: Detach "Patient's Instructions for Use" from package insert and distribute with product.

Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray)

Obey the precautions and directions for use

DESCRIPTION:
Ipratropium bromide nasal solution 0.06% (Nasal Spray) is a metered-dose, manual pump spray of ipratropium bromide monohydrate. It is an anticholinergic agent chemically described as 1-(2, 6-dimethyl-4-piperidinyl)-2, 3-dihydro-1H-isoindol-1-one bromide and exists in an ionized state as a quaternary ammonium compound. It is an in vivo sympatholytic agent which, based on animal studies, appears to inhibit vagally-mediated reflexes (i.e. it has a parasympatholytic effect).

CLINICAL PHARMACOLOGY: Mechanism of Action: Ipratropium bromide is an anticholinergic (parasympatholytic) agent which, based on animal studies, appears to inhibit vagally-mediated reflexes by antagonizing the action of acetylcholine, the transmitter agent released at the postganglionic cholinergic nerve endings in autonomic ganglia. Inhibition of these reflexes results in smooth muscle relaxation and reduced mucous gland secretion. In vitro studies of isolated guinea pig tracheal smooth muscle (unpubl. data) have shown that ipratropium bromide is equipotent with atropine in inhibiting carbachol-induced contractions.

Pharmacodynamics: Ipratropium bromide is a partially reversible and competitive inhibitor of muscarinic receptor activity. The extent of inhibition with ipratropium bromide nasal solution 0.06% (Nasal Spray) in nasal and ocular preparations has been determined in a number of controlled clinical studies in which the drug was compared with placebo, an antihistamine, or other decongestant nasal sprays. The mechanism of action in humans is not fully understood.

CONTRAINDICATIONS: Ipratropium bromide nasal solution 0.06% (Nasal Spray) is contraindicated in patients with a known sensitivity to ipratropium bromide. Patients with a history of asthma or bronchial hyperactivity may experience an increased frequency of bronchospastic attacks.

WARNING: Instruct patients to use the nasal spray only as directed. In accordance with FDA labeling requirements, the nasal spray is not intended for use by patients with a known sensitivity to ipratropium bromide. The nasal spray is a sympatholytic agent that may cause dryness of the mucous membranes, may cause epigastric or paralytic ileus, and may cause drowsiness or dizziness. The nasal spray may cause an increase in heart rate, blood pressure and anti-cholinergic side effects such as dry mouth, blurred vision and urinary retention. These effects may be particularly pronounced in patients who are elderly or who have heart disease. The nasal spray should not be used in patients who have asthma, narrow-angle glaucoma, pyloric stenosis, or prostatic hyperplasia.

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Drug-Drug Interactions: No specific pharmacokinetic studies were conducted to evaluate potential drug interactions.

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Ipratropium bromide nasal solution 0.06% (Nasal Spray) is supplied in a white plastic multidose inhaler with a white plastic nasal cap, a white plastic pump, and a yellow diaphragm. It is supplied in 12 doses, which is equivalent to 6 doses of 2 sprays (84 mcg) per nostril. Each dose contains 27.1 mcg of ipratropium bromide (equivalent to 24.1 mcg ipratropium base) delivered by nasal administration; however the portion which may be excreted in human milk is unknown.

DOSAGE AND ADMINISTRATION: For symptomatic relief of rhinorrhea associated with the common cold, the recommended dose is 2 sprays (84 mcg) per nostril three times a day (total dose of 504 mcg/day).

In adults and children 12 years of age and older, 2 sprays (84 mcg) per nostril three times a day (total dose of 504 mcg/day) is recommended.

In children 6-12 years of age, 1 spray (42 mcg) per nostril three times a day (total dose of 216 mcg/day) is recommended.

In children 5 years of age and younger, 1 spray (42 mcg) per nostril two times a day (total dose of 144 mcg/day) is recommended.

Ipratropium bromide nasal solution is not recommended for use in children younger than 5 years of age.

How Supplied: Ipratropium bromide nasal solution 0.06% (Nasal Spray) is supplied in bottles containing 12 doses. Each bottle contains 27.1 mcg of ipratropium bromide (equivalent to 24.1 mcg ipratropium base) delivered by nasal administration.

ADVERSE REACTIONS: In clinical trials, the most common adverse reactions reported for patients who received ipratropium bromide nasal solution 0.06% (Nasal Spray) at the recommended dose of 84 mcg per nostril, or vehicle, administered three times a day for three weeks, were nasal burning, conjunctivitis, coughing, dizziness, hoarseness, palpitation, pharyngitis, tachycardia, epistaxis, and face, generalized urticaria (including giant urticaria), laryngospasm, and anaphylactic reactions. There were no reports of allergic-type reactions in the controlled clinical trials with ipratropium bromide nasal solution 0.06% (Nasal Spray) and vehicle.

Ipratropium bromide nasal solution 0.06% (Nasal Spray) had an adverse event profile similar to that observed in adult patients. When ipratropium bromide nasal solution was used concomitantly with other intranasal decongestants (0.05% oxymetazoline hydrochloride) in 127 patients 65 years of age or older, the incidence of common adverse events did not change.