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Atrovent Nasal Spray .06 (Ipratropium Bromide Nasal Spray .06)

??? ??????: 30 ??????/?????? 2017

Adverse reaction information on ATROVENT Nasal Spray 0.06% in patients with the common cold was derived from two multicenter, vehicle-controlled clinical trials involving 1,276 patients (195 patients on ATROVENT Nasal Spray 0.03%, 352 patients on ATROVENT Nasal Spray 0.06%, 189 patients on ATROVENT Nasal Spray 0.12%, 351 patients on vehicle and 189 patients receiving no treatment).

Table 1 shows adverse events reported for patients who received ATROVENT Nasal Spray 0.06% at the recommended dose of 84 mcg per nostril, or vehicle, administered three or four times daily, where the incidence is 1% or greater in the ATROVENT group and higher in the ATROVENT group than in the vehicle group.

[1] Table 1 - % of Patients with Common Cold Reporting Events

Vehicle Control	Atrovent® (ipratropium bromide) Nasal Spray 0.06%	
351	352	No. of Patients
2.3%	8.2%	[2]Epistaxis
2.8%	4.8%	Nasal Dryness
0.3%	1.4%	Dry Mouth/Throat
0.0%	1.1%	Nasal Congestion
This table includes adverse events for which the incidence was 1% [1] or greater in the ATROVENT group and higher in the ATROVENT group than in the vehicle group. Epistaxis reported by 5.4% of ATROVENT patients and 1.4% of [2] vehicle patients, blood-tinged nasal mucus by 2.8% of ATROVENT patients and 0.9% of vehicle patients.		

ATROVENT Nasal Spray 0.06% was well tolerated by most patients. The most frequently reported adverse events were transient episodes of nasal dryness or epistaxis. The majority of these adverse events (96%) were mild or moderate in nature, none was considered serious, and none resulted in hospitalization. No patient required treatment for nasal dryness, and only three patients (< 1%) required treatment for epistaxis, which consisted of local application of pressure or a moisturizing agent (e.g., petroleum jelly). No patient receiving ATROVENT Nasal Spray 0.06% was discontinued from the trial due to either nasal dryness or bleeding.

Adverse events reported by less than 1% of the patients receiving ATROVENT Nasal Spray 0.06% during the controlled clinical trials that are potentially related to ATROVENT's local effects or systemic anticholinergic effects include: taste perversion, nasal burning, conjunctivitis, coughing, dizziness, hoarseness, palpitation, pharyngitis, tachycardia, thirst, tinnitus, and blurred vision. No controlled trial was conducted to address the relative incidence of adverse events for three times daily versus four times daily therapy.

Nasal adverse events seen in the clinical trial with seasonal allergic rhinitis (SAR) patients (see Table 2) were similar to those seen in the common cold trials. Additional events were reported at a higher rate in the SAR trial due in part to the longer duration of the trial and the inclusion of Upper Respiratory Tract Infection (URI) as an adverse event. In common cold trials, URI was the disease under study and not an adverse event.

[1]Table 2 - % of Patients with SAR Reporting Events

Vehicle Control	Atrovent® (ipratropium bromide) Nasal Spray 0.06%

211	218	No. of Patients
3.3%	6.0%	[2]Epistaxis
3.8%	5.0%	Pharyngitis
3.3%	5.0%	URI
0.9%	4.6%	Nasal Dryness
0.5%	4.1%	Headache
0.0%	4.1%	Dry Mouth/Throat
1.4%	3.7%	Taste Perversion
2.8%	2.8%	Sinusitis
0.9%	1.8%	Pain
0.5%	1.8%	Diarrhea

This table includes adverse events for which the incidence was 1% [1] or greater in the ATROVENT group and higher in the ATROVENT group than in the vehicle group.

Epistaxis reported by 3.7% of ATROVENT patients and 2.4% of [2] vehicle patients, blood-tinged nasal mucus by 2.3% of ATROVENT patients and 1.9% of vehicle patients.

There were no reports of allergic-type reactions in the controlled clinical common cold and SAR trials.

Post-Marketing Experience

Allergic-type reactions such as skin rash, angioedema of the throat, tongue, lips and face, generalized urticaria (including giant urticaria), laryngospasm, and anaphylactic reactions have been reported with ATROVENT Nasal Spray 0.06% and for other ipratropium bromide-containing products, with positive rechallenge in some cases.

Additional side effects identified from the published literature and/or post-marketing surveillance on the use of ipratropium bromide-containing products (singly or in combination with albuterol), include: urinary retention, prostatic disorders, mydriasis, cases of precipitation or worsening of narrow-angle glaucoma, acute eye pain, ocular irritation, wheezing, dryness of the oropharynx, tachycardia, edema, gastrointestinal distress (diarrhea, nausea, vomiting), bowel obstruction, and constipation.

After oral inhalation of ipratropium bromide in patients suffering from COPD/Asthma supraventricular tachycardia and atrial fibrillation have been reported.