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Azelastine Hydrochloride Nasal Spray (Astepro)

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

]. **WARNINGS AND PRECAUTIONS**Use of ASTEPRO has been associated with somnolence [see

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect rates observed in practice.

ASTEPRO 0.1%

The safety data described below reflect exposure to ASTEPRO 0.1% in 975 patients 6 months of age and older from 4 clinical trials of 2 weeks to 12 months duration. In a 2-week, double-blind, placebo-controlled, and active-controlled (Astelin® Nasal Spray; azelastine hydrochloride) clinical trial, 285 patients (115 males and 170 females) 12 years of age and older with seasonal allergic rhinitis were treated with ASTEPRO 0.1% one or two sprays per nostril daily. In the 12 month open-label, active-controlled (Astelin Nasal Spray) clinical trial, 428 patients (207 males and 221 females) 12 years of age and older with perennial allergic rhinitis and/or nonallergic rhinitis were treated with ASTEPRO 0.1% two sprays per nostril twice daily. In a 4-week, double-blind, placebo-controlled clinical trial, 166 patients (101 males and 65 females) ages 6 to 11 years of age with perennial allergic rhinitis, with or without concomitant seasonal allergic rhinitis, were treated with ASTEPRO 0.1% one spray per nostril twice daily. In a 4-week clinical trial, 96 patients (51 males and 45 females) ages 6 months to 5 years of age with seasonal and/or perennial allergic rhinitis were treated with ASTEPRO 0.1% one spray per nostril twice daily. The racial and ethnic distribution for the 4 clinical trials was 80% white, 11% black, 8% Hispanic, 3% Asian, and 2% other.

Adults and Adolescents 12 Years of Age and Older

In the two week clinical trial, 835 patients 12 years of age and older with seasonal allergic rhinitis were treated with one of six treatments: one spray per nostril of either ASTEPRO 0.1%, Astelin Nasal Spray or placebo twice daily; or 2 sprays per nostril of ASTEPRO 0.1%, Astelin Nasal Spray, or placebo twice daily. Overall, adverse reactions were more common in the ASTEPRO 0.1% treatment groups (21-28%) than in the placebo groups (16-20%). Overall, less than 1% of patients discontinued due to adverse reactions and withdrawal due to adverse reactions was similar among the treatment groups.

Table 1 contains adverse reactions reported with frequencies greater than or equal to 2% and more frequently than placebo in patients treated with ASTEPRO 0.1% in the controlled clinical trial described above.

Table 1: Adverse Reactions Reported in ? 2% Incidence in a Placebo-Controlled Trial of 2 Weeks' Duration with ASTEPRO 0.1% in Adult and Adolescent Patients with Seasonal Allergic Rhinitis

	2 sprays twice daily			1 spray twice daily		
Vehicle Placebo (N=138)	Astelin Nasal Spray (N=137)	ASTEPRO 0.1% (N=146)	Vehicle Placebo (N=137)	Astelin Nasal Spray (N=137)	ASTEPRO 0.1% (N=139)	
3 (2%)	11 (8%)	10 (7%)	2 (2%)	13 (10%)	8 (6%)	Bitter Taste
0 (0%)	3 (2%)	4 (3%)	3 (2%)	8 (6%)	3 (2%)	Epistaxis
1 (< 1%)	3 (2%)	4 (3%)	1 (< 1%)	5 (4%)	2 (1%)	Headache
0 (0%)	6 (4%)	2 (1%)	1 (< 1%)	3 (2%)	0 (0%)	Nasal Discomfort
1 (< 1%)	3 (2%)	3 (2%)	1 (< 1%)	1 (< 1%)	0 (0%)	Fatigue
0 (0%)	2 (1%)	3 (2%)	0 (0%)	2 (2%)	2 (1%)	Somnolence

Long-Term (12 Month) Safety Trial

In the 12 month, open-label, active-controlled, long-term safety trial, 862 patients 12 years of age and older with perennial allergic and/or nonallergic rhinitis were treated with ASTEPRO 0.1% two sprays per nostril twice daily or Astelin Nasal Spray two sprays per nostril twice daily. The most frequently reported adverse reactions were headache, bitter taste, epistaxis, and nasopharyngitis and were generally similar between treatment groups. Focused nasal examinations were

performed and showed that the incidence of nasal mucosal ulceration in each treatment group was approximately 1% at baseline and approximately 1.5% throughout the 12 month treatment period. In each treatment group, 5-7% of patients had mild epistaxis. No patients had reports of nasal septal perforation or severe epistaxis. Twenty-two patients (5%) treated with ASTEPRO 0.1% and 17 patients (4%) treated with Astelin Nasal Spray discontinued from the trial due to adverse events.

Children 6 to 11 Years of Age

In a 4 week clinical trial, 489 patients ages 6 to 11 years with perennial allergic rhinitis, with or without concomitant seasonal allergic rhinitis, were treated with either ASTEPRO 0.1%, ASTEPRO 0.15% or placebo, one spray per nostril twice daily. Overall, adverse events were similar in the ASTEPRO 0.15% group (24%), ASTEPRO 0.1% group (26%) and the placebo group (24%). Overall, less than 1% of the combined ASTEPRO groups discontinued due to adverse events.

Table 2 contains adverse reactions reported with frequencies greater than or equal to 2% and more frequently than placebo in children 6 to 11 years of age treated with ASTEPRO 0.1% or ASTEPRO 0.15% in the controlled trial described above.

Table 2: Adverse Reactions Reported in ? 2% Incidence in a Placebo-Controlled Trial of 4 Weeks' Duration with ASTEPRO 0.1% or ASTEPRO 0.15% in Children 6 to 11 Years of Age with Perennial Allergic Rhinitis

	1 spray twice daily		
	Vehicle Placebo (N=162)	ASTEPRO 0.15% (N=161)	ASTEPRO 0.1% (N=166)
Epistaxis	5 (3%)	7 (4%)	8 (5%)
Nasal Discomfort	0 (0%)	7 (4%)	1 (< 1%)
Dysgeusia	1 (< 1%)	6 (4%)	4 (2%)
Upper respiratory infection	3 (2%)	4 (3%)	4 (2%)
Sneezing	2 (1%)	4 (3%)	3 (2%)

Children 6 Months to 5 Years

In a 4 week clinical trial, 191 patients ages 6 months to 5 years with either seasonal and/or perennial allergic rhinitis were treated with either ASTEPRO 0.1% or ASTEPRO 0.15% one spray per nostril twice daily. The most frequently (? 2%) reported adverse reactions were pyrexia, cough, epistaxis, sneezing, dysgeusia, rhinalgia, upper respiratory infection, vomiting, otitis media, contact dermatitis, and oropharyngeal pain. Overall, adverse events were slightly higher in the ASTEPRO 0.15% group (28%) compared to ASTEPRO 0.1% group (21%). Focused nasal examinations were performed and showed no incidence of nasal mucosal ulceration at any time point during the study. No patients had reports of nasal septal perforation. Overall, less than 3% of the combined ASTEPRO groups discontinued due to adverse events.

ASTEPRO 0.15%

The safety data described below reflect exposure to ASTEPRO 0.15% in 2114 patients (6 months of age and older) with seasonal or perennial allergic rhinitis from 10 clinical trials of 2 weeks to 12 months duration. In 8 double-blind, placebo-controlled clinical trials of 2 to 4 weeks duration, 1703 patients (646 males and 1059 females) with seasonal or perennial allergic rhinitis were treated with ASTEPRO 0.15% one or two sprays per nostril once or twice daily. In the 12 month open-label, active-controlled clinical trial, 466 patients (156 males and 310 females) with perennial allergic rhinitis were treated with ASTEPRO 0.15% two sprays per nostril -twice daily. Of these 466 patients, 152 had participated in the 4-week placebo-controlled perennial allergic rhinitis clinical trials. In a 4-week, double-blind, placebo controlled clinical trial, 161 patients (87 males and 74 females) ages 6 to 11 years of age with perennial allergic rhinitis, with or without concomitant seasonal allergic rhinitis, were treated with ASTEPRO 0.15% one spray per nostril twice daily. In a 4-week clinical trial, 95 patients (59 males and 36 females) ages 6 months to 5 years of age with seasonal and/or perennial allergic rhinitis were treated with ASTEPRO 0.15% one spray per nostril twice daily. The racial distribution for the 10 clinical trials was 79% white, 14% black, 2% Asian, and 5% other.

Adults and Adolescents 12 Years of Age and Older

In the 7 placebo controlled clinical trials of 2 to 4 week duration, 2343 patients with seasonal allergic rhinitis and 540 patients with perennial allergic rhinitis were treated with two sprays per nostril of either ASTEPRO 0.15% or placebo once or twice daily. Overall, adverse reactions were more common in the ASTEPRO 0.15% treatment groups (16-31%) than in the placebo groups (11-24%). Overall, less than 2% of patients discontinued due to adverse reactions and withdrawal due to adverse reactions was similar among the treatment groups.

Table 3 contains adverse reactions reported with frequencies greater than or equal to 2% and more frequently than placebo in patients treated with ASTEPRO 0.15% in the seasonal and perennial allergic rhinitis controlled clinical trials.

Table 3: Adverse Reactions with ? 2% Incidence in Placebo-Controlled Trials of 2 to 4 Weeks' Duration with ASTEPRO 0.15% in Adult and Adolescent Patients With Seasonal or Perennial Allergic Rhinitis

	2 sprays once daily		2 sprays twice daily		
	Vehicle Placebo (N=816)	ASTEPRO 0.15% (N=1021)	Vehicle Placebo (N=523)	ASTEPRO 0.15% (N=523)	
Bitter Taste	2 (< 1%)	38 (4%)	5 (1%)	31 (6%)	

7 (1%)	37 (4%)	12 (2%)	18 (3%)	Nasal Discomfort
14 (2%)	21 (2%)	7 (1%)	5 (1%)	Epistaxis
0 (0%)	14 (1%)	1 (< 1%)	9 (2%)	Sneezing

In the above trials, somnolence was reported in < 1% of patients treated with ASTEPRO 0.15% (11 of 1544) or vehicle placebo (1 of 1339).

Long-Term (12 Month) Safety Trial

In the 12 month, open-label, active-controlled, long-term safety trial, 466 patients (12 years of age and older) with perennial allergic rhinitis were treated with ASTEPRO 0.15% two sprays per nostril twice daily and 237 patients were treated with mometasone nasal spray two sprays per nostril once daily. The most frequently reported adverse reactions (> 5%) with ASTEPRO 0.15% were bitter taste, headache, sinusitis, and epistaxis. Focused nasal examinations were performed and no nasal ulcerations or septal perforations were observed. In each treatment group, approximately 3% of patients had mild epistaxis. No patients had reports of severe epistaxis. Fifty-four patients (12%) treated with ASTEPRO 0.15% and 17 patients (7%) treated with mometasone nasal spray discontinued from the trial due to adverse events.

Children 6 months to 11 Years Of Age

See summary under ASTEPRO 0.1%

Postmarketing Experience

During the post approval use of ASTEPRO 0.1% and ASTEPRO 0.15%, the following adverse reactions have been identified. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Adverse reactions reported include: abdominal pain, atrial fibrillation, blurred vision, chest pain, confusion, disturbance or loss of sense of smell and/or taste, dizziness, dyspnea, facial swelling, hypertension, involuntary muscle contractions, nasal burning, nausea, nervousness, palpitations, paresthesia, parosmia, pruritus, rash, sneezing, insomnia, sweet taste, tachycardia, and throat irritation.

Additionally, the following adverse reactions have been identified during the post approval use of the Astelin brand of azelastine hydrochloride 0.1% nasal spray (total daily dose 0.55 mg to 1.1 mg). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Adverse reactions reported include the following: anaphylactoid reaction, application site irritation, facial edema, paroxysmal sneezing, tolerance, urinary retention, and xerophthalmia.