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Azelastine Hydrochloride (Astelin)

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

]. **WARNINGS AND PRECAUTIONS**Use of Astelin Nasal Spray 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.

Seasonal Allergic Rhinitis

Astelin Nasal Spray Two Sprays Per Nostril Twice Daily

Adverse experience information for Astelin Nasal Spray is derived from six placebo-and active-controlled, 2-day to 8-week clinical trials which included 391 patients, 12 years of age and older, with seasonal allergic rhinitis who received Astelin Nasal Spray at a dose of 2 sprays per nostril twice daily. In placebo-controlled efficacy trials, the incidence of discontinuation due to adverse reactions in patients receiving Astelin Nasal Spray and vehicle placebo was 2.2% and 2.8%, respectively.

Table 1 contains adverse reactions that were reported with frequencies ? 2% in the Astelin Nasal Spray 2 sprays per nostril twice daily treatment group and more frequently than placebo.

Table 1: Adverse Reactions Reported in ? 2% Incidence in Placebo-Controlled Trials in Patients with Seasonal Allergic Rhinitis [n (%)]

Vehicle Placebo N = 353	Astelin Nasal Spray N = 391	
2 (0.6%)	77 (19.7%)	Bitter Taste
45 (12.7%)	58 (14.8%)	Headache
19 (5.4%)	45 (11.5%)	Somnolence
6 (1.7%)	16 (4.1%)	Nasal Burning
10 (2.8%)	15 (3.8%)	Pharyngitis
4 (1.1%)	12 (3.1%)	Paroxysmal Sneezing
6 (1.7%)	11 (2.8%)	Dry Mouth
4 (1.1%)	11 (2.8%)	Nausea
5 (1.4%)	9 (2.3%)	Rhinitis
5 (1.4%)	9 (2.3%)	Fatigue
5 (1.4%)	8 (2.0%)	Dizziness
5 (1.4%)	8 (2.0%)	Epistaxis
0 (0.0%)	8 (2.0%)	Weight Increase

Astelin Nasal Spray One Spray Per Nostril Twice Daily

Adverse experience information for Astelin Nasal Spray at a dose of one spray per nostril twice daily is derived from two placebo-controlled 2-week clinical studies which included 276 patients 12 years of age and older with seasonal allergic rhinitis. The incidence of discontinuation due to adverse reactions in patients receiving Astelin Nasal Spray and vehicle placebo was 0.0% and 0.8%, respectively. Bitter taste was reported in 8.3% of patients compared to none in the placebo group. Somnolence was reported in 0.4% of patients compared to none in the placebo group.

A total of 176 patients 5 to 11 years of age were exposed to Astelin Nasal Spray at a dose of 1 spray each nostril twice daily in 3 placebo-controlled studies. In these studies, adverse reactions that occurred more frequently in patients treated with Astelin Nasal Spray than with placebo, and that were not represented in the adult adverse reactions table above include rhinitis/cold symptoms (17.0% vs. 9.5%), cough (11.4% vs. 8.3%), conjunctivitis (5.1% vs. 1.8%), and asthma (4.5% vs. 4.1%).

Adverse Reactions < 2% in Astelin Nasal Spray One or Two Sprays Per Nostril Twice Daily

The following reactions were observed infrequently (< 2% and exceeding placebo incidence) in patients who received Astelin Nasal Spray dosed at 1 or 2 sprays

per nostril twice daily in U.S. clinical trials.

flushing, hypertension, tachycardia. **Cardiovascular:**

contact dermatitis, eczema, hair and follicle infection, furunculosis, skin laceration. **Dermatological:**

constipation, gastroenteritis, glossitis, ulcerative stomatitis, vomiting, increased SGPT, aphthous stomatitis, diarrhea, toothache. **Digestive:**

increased appetite. **Metabolic and Nutritional:**

myalgia, temporomandibular dislocation, rheumatoid arthritis. **Musculoskeletal:**

hyperkinesia, hypoesthesia, vertigo. **Neurological:**

anxiety, depersonalization, depression, nervousness, sleep disorder, thinking abnormal. Respiratory: bronchospasm, coughing, throat burning, **Psychological:** laryngitis, bronchitis, dry throat, nocturnal dyspnea, nasopharyngitis, nasal congestion, pharyngolaryngeal pain, sinusitis, nasal dryness, paranasal sinus hypersecretion, post nasal drip.

conjunctivitis, eye abnormality, eye pain, watery eyes, taste loss. **Special Senses:**

albuminuria, amenorrhea, breast pain, hematuria, increased urinary frequency. **Urogenital:**

allergic reaction, back pain, herpes simplex, viral infection, malaise, pain in extremities, abdominal pain, pyrexia. **Whole Body:**

Vasomotor Rhinitis

Adverse experience information for Astelin Nasal Spray is derived from two placebo-controlled clinical studies which included 216 patients 12 years and older with vasomotor rhinitis who received Astelin Nasal Spray at a dose of 2 sprays per nostril twice daily for up to 28 days. The incidence of discontinuation due to adverse reactions in patients receiving Astelin Nasal Spray and vehicle placebo was 2.8% and 2.9%, respectively.

The following adverse reactions were reported with frequencies ? 2% in the Astelin Nasal Spray treatment group and more frequently than placebo.

Table 2: Adverse Reactions Reported in ? 2% Incidence in Placebo-Controlled Trials in Patients with Vasomotor Rhinitis [n (%)]

Vehicle Placebo N = 210	Astelin Nasal Spray N = 216	
5 (2.4%)	42 (19.4%)	Bitter Taste
16 (7.6%)	17 (7.9%)	Headache
7 (3.3%)	17 (7.9%)	Dysesthesia
5 (2.4%)	12 (5.6%)	Rhinitis
5 (2.4%)	7 (3.2%)	Epistaxis
4 (1.9%)	7 (3.2%)	Sinusitis
2 (1.0%)	7 (3.2%)	Somnolence

Reactions observed infrequently (< 2% and exceeding placebo incidence) in patients who received Astelin Nasal Spray (2 sprays/nostril twice daily) in U.S. clinical trials in vasomotor rhinitis were similar to those observed in U.S. clinical trials in seasonal allergic rhinitis.

In controlled trials involving nasal and oral azelastine hydrochloride formulations, there were infrequent occurrences of hepatic transaminase elevations.

Postmarketing Experience

During the post approval use of Astelin Nasal Spray, 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: anaphylaxis, application site irritation, atrial fibrillation, chest pain, confusion, dyspnea, facial edema, involuntary muscle contractions, nasal sores, palpitations, paresthesia, parosmia, pruritus, rash, disturbance or loss of sense of smell and/or taste, tolerance, urinary retention, vision abnormal and xerophthalmia.