

EXHIBIT C

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **ASTELIN®** safely and effectively. See full prescribing information for **ASTELIN**.

ASTELIN (azelastine hydrochloride) nasal spray
Initial U.S. Approval: 1996

INDICATIONS AND USAGE

Astelin Nasal Spray is an H₁-receptor antagonist indicated for the treatment of the symptoms of seasonal allergic rhinitis in adults and pediatric patients 5 years and older and for the treatment of the symptoms of vasomotor rhinitis in adults and adolescent patients 12 years and older. (1)

DOSAGE AND ADMINISTRATION

- For intranasal use only (2.3)
- Seasonal allergic rhinitis:
 - Pediatric patients 5 to 11 years of age: 1 spray per nostril twice daily (2.1)
 - Adults and adolescents 12 years of age and older: 1 or 2 sprays per nostril twice daily (2.1)
- Vasomotor rhinitis: 2 sprays per nostril twice daily in adults and adolescents 12 years of age and older (2.2)
- Prime Astelin Nasal Spray before initial use and when it has not been used for 3 or more days (2.3)

DOSAGE FORMS AND STRENGTHS

Astelin Nasal Spray: 137 mcg of azelastine hydrochloride in each 0.137 mL spray. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Somnolence: Avoid engaging in hazardous occupations requiring complete mental alertness such as driving or operating machinery when taking Astelin Nasal Spray. (5.1)
- Alcohol and other central nervous system (CNS) depressants: Avoid concurrent use with Astelin Nasal Spray because further decreased alertness and impairment of CNS performance may occur. (5.1)

ADVERSE REACTIONS

The most common adverse reactions (≥2% incidence) are: bitter taste, headache, somnolence, dysesthesia, rhinitis, nasal burning, pharyngitis, epistaxis, sinusitis, paroxysmal sneezing, nausea, dry mouth, fatigue, dizziness, and weight increase. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-866-210-5954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2014

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Astelin Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis in adults and pediatric patients 5 years and older, and for the treatment of the symptoms of vasomotor rhinitis in adults and adolescent patients 12 years and older.

2 DOSAGE AND ADMINISTRATION

2.1 Seasonal Allergic Rhinitis

The recommended dosage of Astelin Nasal Spray in adults and adolescent patients 12 years and older with seasonal allergic rhinitis is one or two sprays per nostril twice daily. The recommended dosage of Astelin Nasal Spray in pediatric patients 5 years to 11 years of age is one spray per nostril twice daily.

2.2 Vasomotor Rhinitis

The recommended dosage of Astelin Nasal Spray in adults and adolescent patients 12 years and older with vasomotor rhinitis is two sprays per nostril twice daily.

2.3 Important Administration Instructions

Administer Astelin Nasal Spray by the intranasal route only.

Priming: Prime Astelin Nasal Spray before initial use by releasing 4 sprays or until a fine mist appears. When Astelin Nasal Spray has not been used for 3 or more days, reprime with 2 sprays or until a fine mist appears. Avoid spraying Astelin Nasal Spray into the eyes.

3 DOSAGE FORMS AND STRENGTHS

Astelin Nasal Spray is a nasal spray solution. Each spray of Astelin Nasal Spray delivers a volume of 0.137 mL solution containing 137 mcg of azelastine hydrochloride.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Somnolence in Activities Requiring Mental Alertness

In clinical trials, the occurrence of somnolence has been reported in some patients taking Astelin Nasal Spray [see *Adverse Reactions (6.1)*]. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness and motor coordination such as

operating machinery or driving a motor vehicle after administration of Astelin Nasal Spray. Concurrent use of Astelin Nasal Spray with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur [see *Drug Interactions (7.1)*].

6 ADVERSE REACTIONS

Use of Astelin Nasal Spray has been associated with somnolence [see *Warnings and Precautions (5.1)*].

6.1 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 $\geq 2\%$ in the Astelin Nasal Spray 2 sprays per nostril twice daily treatment group and more frequently than placebo.

Table 1: Adverse Reactions Reported in $\geq 2\%$ Incidence in Placebo-Controlled Trials in Patients with Seasonal Allergic Rhinitis [n (%)]		
	Astelin Nasal Spray N = 391	Vehicle Placebo N = 353
Bitter Taste	77 (19.7%)	2 (0.6%)
Headache	58 (14.8%)	45 (12.7%)
Somnolence	45 (11.5%)	19 (5.4%)
Nasal Burning	16 (4.1%)	6 (1.7%)
Pharyngitis	15 (3.8%)	10 (2.8%)
Paroxysmal Sneezing	12 (3.1%)	4 (1.1%)
Dry Mouth	11 (2.8%)	6 (1.7%)
Nausea	11 (2.8%)	4 (1.1%)
Rhinitis	9 (2.3%)	5 (1.4%)

Fatigue	9 (2.3%)	5 (1.4%)
Dizziness	8 (2.0%)	5 (1.4%)
Epistaxis	8 (2.0%)	5 (1.4%)
Weight Increase	8 (2.0%)	0 (0.0%)

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.

Cardiovascular: flushing, hypertension, tachycardia.

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

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

Metabolic and Nutritional: increased appetite.

Musculoskeletal: myalgia, temporomandibular dislocation, rheumatoid arthritis.

Neurological: hyperkinesia, hypoesthesia, vertigo.

Psychological: anxiety, depersonalization, depression, nervousness, sleep disorder, thinking abnormal.

Respiratory: bronchospasm, coughing, throat burning, laryngitis, bronchitis, dry throat, nocturnal dyspnea, nasopharyngitis, nasal congestion, pharyngolaryngeal pain, sinusitis, nasal dryness, paranasal sinus hypersecretion, post nasal drip.

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

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

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