Azelastine Hydrochloride Nasal Spray

Azelastine Hydrochloride 0.1% Nasal Spray

IN-0234-03
Rev. 1/2014

DOSAGE AND ADMINISTRATION

Azelastine Hydrochloride Nasal Spray is an H₁-receptor antagonist indicated for the relief of the symptoms of seasonal and perennial allergic rhinitis in patients 6 years of age and older. (1.1)

For intranasal use only (2.3).

Seasonal allergic rhinitis:
- Azelastine Hydrochloride Nasal Spray 0.1% and 0.15%: 1 spray per nostril twice daily in children 6 to 11 years of age (2.1)
- Azelastine Hydrochloride Nasal Spray 0.15%: 1 or 2 sprays per nostril twice daily in adults and adolescents 12 years of age and older (2.1)
- Azelastine Hydrochloride Nasal Spray 0.15%: 2 sprays per nostril once daily in adults and adolescents 12 years of age and older (2.1)

Perennial allergic rhinitis:
- Azelastine Hydrochloride Nasal Spray 0.1% and 0.15%: 1 spray per nostril twice daily in children 6 to 11 years of age (2.2)
- Azelastine Hydrochloride Nasal Spray 0.15%: 2 sprays per nostril twice daily in adults and adolescents 12 years of age and older (2.2)

Prime Azelastine Hydrochloride Nasal Spray before initial use and when it has not been used for 3 or more days. (2.5)

DOSAGE FORMS AND STRENGTHS

Each spray of Azelastine Hydrochloride Nasal Spray 0.15% delivers a volume of 0.137 mL solution containing 137 mcg of azelastine hydrochloride. Azelastine Hydrochloride Nasal Spray 0.1% delivers a volume of 0.137 mL solution containing 205.5 mcg of azelastine hydrochloride.

CONTRAINdications

None. (4)

WARNINGS AND PRECAUTIONS

- Somnolence may occur. Avoid engaging in hazardous occupations requiring complete mental alertness such as driving or operating machinery when taking Azelastine Hydrochloride Nasal Spray (5.1)
- Avoid concurrent use of alcohol or other central nervous system (CNS) depressants with Azelastine Hydrochloride 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, nasal discomfort, epistaxis, headache, sneezing, fatigue, somnolence, and upper respiratory infection (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Wallace Pharmaceuticals Inc. at 1-800-619-6344 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: 1/2014

OVERDOSAGE

None.

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12.2 Pharmacodynamics
12.3 Pharmacokinetics

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Allergic Rhinitis

Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% is indicated for the relief of the symptoms of seasonal and perennial allergic rhinitis in patients 6 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Seasonal Allergic Rhinitis

In children 6 to 11 years of age, the recommended dose of Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% is 1 spray per nostril twice daily.

In adults and adolescents 12 years of age and older, the recommended dose of Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% is 1 spray per nostril twice daily.

2.2 Perennial Allergic Rhinitis

In children 6 to 11 years of age, the recommended dose of Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% is 1 spray per nostril twice daily.

In adults and adolescents 12 years of age and older, the recommended dose of Azelastine Hydrochloride Nasal Spray 0.15% is 2 sprays per nostril twice daily.

2.3 Important Administration Instructions

Administer Azelastine Hydrochloride Nasal Spray by the intranasal route only.

Primings: Prime Azelastine Hydrochloride Nasal Spray before initial use by releasing 6 sprays or until a fine mist appears. When Azelastine Hydrochloride Nasal Spray has not been used for 3 or more days, reprime with 2 sprays or until a fine mist appears. Avoid spraying Azelastine Hydrochloride Nasal Spray into the eyes.

3 DOSAGE FORMS AND STRENGTHS

Azelastine Hydrochloride Nasal Spray is a nasal spray solution. Each spray of Azelastine Hydrochloride Nasal Spray 0.1% delivers a volume of 0.137 mL solution containing 137 mcg of azelastine hydrochloride. Each spray of Azelastine Hydrochloride Nasal Spray 0.15% delivers a volume of 0.137 mL solution containing 205.5 mcg of azelastine hydrochloride.

CONTRAINDICATIONS

None.
In the above trials, somnolence was reported in <1% of patients treated with Azelastine Hydrochloride Nasal Spray 0.1% 2 sprays per nostril twice daily and 237 patients were treated with mometasone nasal spray two sprays per nostril once daily. The overall occurrence of somnolence was lower than 0.5%. In this trial, patients treated with Azelastine Hydrochloride Nasal Spray 0.15% 2 sprays per nostril twice daily were reported to be similar. 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 Azelastine Hydrochloride Nasal Spray 0.15% in the controlled clinical trial described above.

Table 2 contains adverse reactions reported in the 4-week, placebo-controlled perennial allergic rhinitis trials. 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 Azelastine Hydrochloride Nasal Spray 0.15% 2 sprays per nostril twice daily and 237 patients were treated with mometasone nasal spray two sprays per nostril once daily. The overall occurrence of somnolence was lower than 0.5%. In this trial, patients treated with Azelastine Hydrochloride Nasal Spray 0.15% 2 sprays per nostril twice daily were reported to be similar. Overall, less than 1% 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 Azelastine Hydrochloride Nasal Spray 0.15% in the seasonal and perennial allergic rhinitis controlled clinical trials.

### 8.1 Pregnancy

This drug is not known to be excreted into human milk. Azelastine Hydrochloride Nasal Spray should be used during pregnancy only if the potential benefit justifies the possible risk to the fetus.

### 8.2 Lactation

Azelastine Hydrochloride Nasal Spray is not known to be excreted into human milk. Azelastine Hydrochloride Nasal Spray should be used during lactation only if the potential benefit justifies the possible risk to the nursing infant.

### 8.3 Nursing Mothers

Azelastine Hydrochloride Nasal Spray should be used during pregnancy only if the potential benefit justifies the possible risk to the fetus.

### 8.4 Pediatric Use

Azelastine Hydrochloride Nasal Spray has not been adequately studied in children.

### 8.5 Geriatric Use

Clinical trials of Azelastine Hydrochloride Nasal Spray did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger patients. Other clinical studies have not shown that age affects the geriatric use of Azelastine Hydrochloride Nasal Spray.

### 10 OVERDOSAGE

There have been no reported overdosages with Azelastine Hydrochloride Nasal Spray. Acute overdosage by adults with this dosing form is unlikely to result in clinically significant adverse events, other than those related to excessive sedation. In one 30-mL bottle of Azelastine Hydrochloride Nasal Spray 0.15% contains up to 30 mg of azelastine hydrochloride and one 30-mL bottle of Azelastine Hydrochloride Nasal Spray 0.15% contains up to 45 mg of azelastine hydrochloride. Clinical trials in adults with single doses of the oral formulation of azelastine hydrochloride (up to 16 mg) have not resulted in increased incidence of serious adverse reactions. There is no testing of frequent or prolonged overdosage with this dosage form.

### 11 DESCRIPTION

Azelastine Hydrochloride Nasal Spray 0.1%, 137 micrograms (mcg), is an antihistamine formulated as a metered-spray solution for intranasal administration. Azelastine Hydrochloride Nasal Spray 0.15%, 205.5 micrograms (mcg), is formulated as a metered-spray solution for intranasal administration.
Azelastine hydrochloride occurs as a white, almost odorless, crystalline powder with a bitter taste. It has a molecular weight of 418.37. It is sparingly soluble in water, methanol, and propylene glycol and slightly soluble in ethanol, octanol, and glycine. It has a melting point of about 225°C and the pH of a saturated solution is between 5.0 to 5.4. Its chemical name is (±)-1-(2H)-phthalazinone, 4-[[(4-chlorophenyl)methyl]2-(hexahydro-1-methyl-1H-azepin-4-yl)]-monohydrochloride. Its molecular formula is C23H24ClNO2.HCl with the following chemical structure:

Azelastine Hydrochloride Nasal Spray 0.1% contains 0.1% azelastine hydrochloride in an isotonic aqueous solution containing sorbitol, sucrose, hypromellose, sodium citrate, edetate disodium, benzalkonium chloride (125 mcg/mL), and purified water (pH 6.4).

Azelastine Hydrochloride Nasal Spray 0.15% contains 0.15% azelastine hydrochloride in an isotonic aqueous solution containing sorbitol, sucrose, hypromellose, sodium citrate, edetate disodium, benzalkonium chloride (125 mcg/mL), and purified water (pH 6.4).

In a placebo-controlled trial (95 patients with allergic rhinitis), there was no evidence of an effect of azelastine hydrochloride nasal spray (2 sprays per nostril twice daily for 56 days) on cardiac repolarization as represented by the corrected QT interval (QTc) of the electrocardiogram. Following multiple dose oral administration of azelastine 4 mg or 8 mg twice daily, the mean change in QTc was 7.2 msec and 3.6 msec, respectively.

Interaction studies investigating the cardiac repolarization effects of concomitantly administered oral azelastine hydrochloride and erythromycin or ketoconazole were conducted. Oral erythromycin had no effect on azelastine pharmacokinetics or QTc based on analysis of serial electrocardiograms. Ketoconazole 200 mg twice daily dosed for 1 week decreased the azelastine hydrochloride nasal spray (2 sprays per nostril twice daily for 14 days) bioavailability of azelastine hydrochloride is approximately 40% after intranasal administration.

Azelastine Hydrochloride Nasal Spray 0.15% was 12 to 83 years of age (64% female; 36% male; 81% white, 12% black, <2% Asian, 5% other; 23% Hispanic, 77% non-Hispanic). Assessment of efficacy was based on the TNSS described above, and other supportive secondary efficacy variables. The primary endpoint definition was the mean change from baseline rTNSS (mean ± SD) for each treatment arm.

**Table 4. Mean Change from Baseline in Reflective TNSS over 2 Weeks**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n Baseline Change from Baseline</th>
<th>Change from Placebo</th>
<th>Life Years Saved</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.1%</td>
<td>146</td>
<td>18.0</td>
<td>-5.0</td>
<td>-3.2</td>
</tr>
<tr>
<td>Azelastine Nasal Spray</td>
<td>138</td>
<td>18.2</td>
<td>-2.8</td>
<td></td>
</tr>
<tr>
<td>One spray twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td>Azelastine Nasal Spray</td>
<td>153</td>
<td>17.9</td>
<td>-3.9</td>
<td>-0.9</td>
</tr>
<tr>
<td><strong>Trial 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>153</td>
<td>18.2</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td>Azelastine Nasal Spray</td>
<td>153</td>
<td>17.9</td>
<td>-3.9</td>
<td>-0.9</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td><strong>Trial 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td>Azelastine Nasal Spray</td>
<td>153</td>
<td>17.9</td>
<td>-3.9</td>
<td>-0.9</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td><strong>Trial 4</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
<tr>
<td>Azelastine Nasal Spray</td>
<td>153</td>
<td>17.9</td>
<td>-3.9</td>
<td>-0.9</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>153</td>
<td>18.1</td>
<td>-4.3</td>
<td>-1.2</td>
</tr>
</tbody>
</table>

The efficacy and safety of Azelastine Hydrochloride Nasal Spray 0.1% was evaluated in a 2-week, randomized, multicenter, double-blind, placebo-controlled clinical trial including 834 adult and adolescent patients (12 years or older with symptoms of seasonal allergic rhinitis). The population was 12 to 83 years of age (60% female; 46% male; 69% white; 15% black; 12% Hispanic, 2% Asian, 1% other).

Patients were randomized to one of six treatment groups: 1 spray per nostril of either Azelastine Hydrochloride Nasal Spray 0.1%, Azelastine (azelastine hydrochloride) Nasal Spray or vehicle placebo twice daily; or 2 sprays per nostril of Azelastine Hydrochloride Nasal Spray 0.1%, Azelastine (azelastine hydrochloride) Nasal Spray or vehicle placebo twice daily.

Assessment of efficacy was based on the 12-hour reflect total nasal symptom score (rTNSS) assessed daily in the morning and evening, and the mean change from the primary endpoint for the primary efficacy endpoints, the difference was statistically significant.

The efficacy and safety of Azelastine Hydrochloride Nasal Spray 0.1% one spray per nostril twice daily for seasonal allergic rhinitis is supported by two, 2-week, placebo-controlled clinical trials with Azelastine (azelastine hydrochloride) Nasal Spray in 413 patients with seasonal allergic rhinitis. In these trials, efficacy was assessed using the TNSS (described above).

The efficacy and safety of Azelastine Hydrochloride Nasal Spray 0.15% was evaluated in five randomized, multicenter, double-blind, placebo-controlled clinical trials in 2499 adult and adolescent patients with seasonal allergic rhinitis. The population of the trials was 12 to 83 years of age (64% female; 36% male; 81% white, 12% black, <2% Asian, 5% other; 23% Hispanic, 77% non-Hispanic). Assessment of efficacy was based on the rTNSS, ITNSS as described above, and other supportive secondary efficacy variables. The primary endpoint definition was the mean change from baseline rTNSS over 2 weeks.
decreases in rTNSS compared to placebo. There was no difference between the two active-treatment baseline rTNSS over 4 weeks (Table 7). Both active treatments demonstrated statistically significant greater decrease in rTNSS than placebo and the difference was statistically significant (Table 6).

Hydrochloride Nasal Spray 0.15%, Azelastine Hydrochloride Nasal Spray 0.1%, and vehicle placebo dosed supportive secondary efficacy variables. The primary efficacy endpoint was the mean change from baseline alertness and motor coordination such as driving or operating machinery after administration of Azelastine Hydrochloride Nasal Spray [see Warnings and Precautions (5.1)].

14.2 Perennial Allergic Rhinitis
Azelastine Hydrochloride Nasal Spray 0.1% and 0.15%

The efficacy and safety of Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% in children 6 to 11 years of age with seasonal allergic rhinitis was evaluated in a clinical study that enrolled pediatric patients with perennial allergic rhinitis, with or without concomitant seasonal allergic rhinitis (described below in Section 14.2).

Table 6. Mean Change from Baseline in Reflective TNSS over 4 Weeks*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>Baseline Mean</th>
<th>Change from Baseline Mean</th>
<th>Difference From Placebo Mean</th>
<th>Difference From Placebo P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two sprays twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>200</td>
<td>15.8</td>
<td>-4.0</td>
<td>-0.9</td>
<td>0.03</td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.1%</td>
<td>194</td>
<td>15.5</td>
<td>-3.8</td>
<td>-0.7</td>
<td>0.08</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>196</td>
<td>14.7</td>
<td>-3.1</td>
<td>-0.6</td>
<td>0.21</td>
</tr>
<tr>
<td>*Sum of AM and PM rTNSS for each day (Maximum score=24) and averaged over the 28 day treatment period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The efficacy and safety of Azelastine Hydrochloride Nasal Spray 0.1% and 0.15% pediatric patients 6 to 11 years of age with perennial allergic rhinitis, with or without concomitant seasonal allergic rhinitis, was evaluated in a randomized, double-blind, placebo-controlled clinical trial in 486 patients. All patients received one spray per nostril twice daily. The study population was 55% males and 45% females; 78% white, 13% black, 3% Asian, and 6% other. Assessment of efficacy was based on the 12-hour reflective total nasal symptom score (rTNSS) assessed daily in the morning and the evening, the instantaneous total nasal symptom score (iTNSS), and other supportive secondary efficacy variables. The primary efficacy endpoint was the mean change from baseline rTNSS over 4 weeks. The one-4 week perennial allergic rhinitis trial evaluated the efficacy of Azelastine Hydrochloride Nasal Spray 0.15%, Azelastine Hydrochloride Nasal Spray 0.1%, and vehicle placebo dosed at 2 sprays per nostril twice daily. In this trial, Azelastine Hydrochloride Nasal Spray 0.15% demonstrated a greater decrease in rTNSS than placebo and the difference was statistically significant (Table 6).

Azelastine Hydrochloride Nasal Spray is supplied as a 30-mL package (NDC 51525-0234-3) containing 45 mg (1.5 mg/mL) of azelastine hydrochloride. After priming [see Dosage and Administration (2.3)], each spray delivers a fine mist containing a mean volume of 0.137 mL solution containing 205.5 mcg of azelastine hydrochloride. The correct amount of medication in each spray cannot be assured before the initial priming and after 200 sprays have been used.

**Table 5. Mean Change from Baseline AM Instantaneous TNSS over 2 Weeks*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>Baseline Mean</th>
<th>Change from Baseline Mean</th>
<th>Difference From Placebo Mean</th>
<th>Difference From Placebo P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays per nostril twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>200</td>
<td>6.1</td>
<td>-1.3</td>
<td>-0.2</td>
<td>0.15</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>204</td>
<td>6.3</td>
<td>-1.1</td>
<td>-0.2</td>
<td>0.15</td>
</tr>
<tr>
<td>Trial 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays per nostril twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>200</td>
<td>6.7</td>
<td>-1.4</td>
<td>-0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>206</td>
<td>6.3</td>
<td>-0.7</td>
<td>-0.2</td>
<td>0.15</td>
</tr>
<tr>
<td>Trial 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two sprays per nostril twice daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azelastine Hydrochloride Nasal Spray 0.15%</td>
<td>251</td>
<td>8.9</td>
<td>-1.4</td>
<td>-0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vehicle Placebo</td>
<td>254</td>
<td>8.9</td>
<td>-0.8</td>
<td>-0.3</td>
<td>0.15</td>
</tr>
<tr>
<td>*AM iTNSS for each day (Maximum score=12) and averaged over the 14-day treatment period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PATIENT INFORMATION**

Azelastine Hydrochloride [a-Zel-as-teen HYE-droe-KLOR-ide] Nasal Spray 0.1% Nasal Spray 0.15%

**Important: For use in your nose only.**

**What is Azelastine Hydrochloride Nasal Spray?**
- Azelastine Hydrochloride Nasal Spray is a prescription medicine used to treat symptoms of seasonal and year-round allergic rhinitis in people 6 and older.
- Azelastine Hydrochloride Nasal Spray may help to reduce your nasal symptoms including stuffy nose, runny nose, itching and sneezing.

It is not known if Azelastine Hydrochloride Nasal Spray is safe and effective in children under 6 years of age.

**What should I tell my healthcare provider before using Azelastine Hydrochloride Nasal Spray?**
- allergic to any of the ingredients in Azelastine Hydrochloride Nasal Spray. See the end of this leaflet for a complete list of ingredients in Azelastine Hydrochloride Nasal Spray.
- pregnant, or plan to become pregnant. It is not known if Azelastine Hydrochloride Nasal Spray is safe and effective in children under 6 years of age.
- breastfeeding, or plan to breastfeed. It is not known if Azelastine Hydrochloride Nasal Spray is safe and effective in children under 6 years of age.

**What should I avoid while using Azelastine Hydrochloride Nasal Spray?**
- Azelastine Hydrochloride Nasal Spray may help to reduce your nasal symptoms including stuffy nose, runny nose, itching and sneezing.
- do not drink alcohol or take other medicines that may cause you to feel sleepy while using Azelastine Hydrochloride Nasal Spray. It may make your sleepiness worse.
What are the possible side effects of Azelastine Hydrochloride Nasal Spray?
The most common side effects of Azelastine Hydrochloride Nasal Spray include:
- unusual bitter taste
- nose pain or discomfort
- nosebleeds
- headache
- sneezing
- fatigue
- sleepiness
- upper respiratory tract infections

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Azelastine Hydrochloride Nasal Spray. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Azelastine Hydrochloride Nasal Spray?
- Keep Azelastine Hydrochloride Nasal Spray upright at 68°F to 77°F (20°C to 25°C).
- Do not freeze Azelastine Hydrochloride Nasal Spray.
- Do not use Azelastine Hydrochloride Nasal Spray after the expiration date “EXP” on the medicine label and box.

Keep Azelastine Hydrochloride Nasal Spray and all medicines out of reach of children.

General information about the safe and effective use of Azelastine Hydrochloride Nasal Spray.
Medicines are sometimes prescribed for conditions other than those listed in a Patient Information leaflet. Do not use Azelastine Hydrochloride Nasal Spray for a condition for which it was not prescribed. Do not give Azelastine Hydrochloride Nasal Spray to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Azelastine Hydrochloride Nasal Spray. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Azelastine Hydrochloride Nasal Spray that is written for health professionals.

For more information call 1-800-619-6344.

What are the ingredients in Azelastine Hydrochloride Nasal Spray?
Active ingredient: azelastine hydrochloride
Inactive ingredients: sorbitol, sucralose, hypromellose, sodium citrate, edetate disodium, benzalkonium chloride, and purified water.

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