

• sleepiness

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 ASTEPRO 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 ASTEPRO Nasal Spray?**

- Keep ASTEPRO Nasal Spray upright at 68° to 77°F (20° to 25°C).
- Do not freeze ASTEPRO Nasal Spray.

**Keep ASTEPRO Nasal Spray and all medicines out of reach of children.**

**General information about ASTEPRO Nasal Spray.**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ASTEPRO Nasal Spray for a condition for which it was not prescribed. Do not give ASTEPRO Nasal Spray to other people, even if they have the same symptoms that you have. It may harm them.

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

For more information, go to [www.Astepro.com](http://www.Astepro.com) or call 1-800-598-4856.

**What are the ingredients in ASTEPRO Nasal Spray?**

Active ingredient: azelastine hydrochloride  
Inactive ingredients: sorbitol, sucralose, hypromellose, sodium citrate, edetate disodium, benzalkonium chloride and purified water.

**Patient Instructions for Use**

**For use in your nose only**

It is important that you read and follow these Patient Instructions for Use carefully to be sure you use ASTEPRO Nasal Spray the right way.

**For the correct dose of medicine:**

- Use ASTEPRO Nasal Spray exactly as prescribed by your healthcare provider.
- Keep your head tilted downward when spraying into your nostril.
- Change nostrils each time you use the spray.
- **Breathe gently and do not tip your head back after using the spray.** This will keep the medicine from running down into your throat. You may get a bitter taste in your mouth.

Follow the instructions below to use your ASTEPRO Nasal Spray pump. See Figure 1.

Figure 1

**Before you use ASTEPRO for the first time, you will need to prime the bottle.**

**To prime:**

1. Remove the blue dust cover over the tip of the bottle and the blue safety clip just under the "shoulders" of the bottle. See Figure 2.

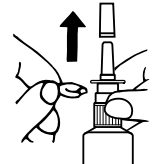


Figure 2

2. Hold the bottle upright with two fingers on the shoulders of the spray pump unit and put your thumb on the bottom of the bottle. Press upward with your thumb and release for the pumping action. Repeat this until you see a fine mist (6 sprays or less). See Figure 3.



Figure 3

3. To get a fine mist you must pump the spray fast and use firm pressure against the bottom of the bottle. If you see a stream of liquid, the spray will not work right and may cause nasal discomfort.
4. If you do not use ASTEPRO Nasal Spray for 3 or more days, you will need to prime the pump with 2 sprays or until you see a fine mist. If you do not see a fine mist, clean the tip of the spray nozzle. See the cleaning section below.

**To Use ASTEPRO Nasal Spray:**

1. Gently blow your nose to clear nostrils.
2. Keep your head tilted downward toward your toes.
3. Place the spray tip ¼ to ½ inch into one nostril. Hold bottle upright and aim the spray tip toward the back of the nose. See Figure 4.
4. Close your other nostril with a finger. Press the pump one time and sniff gently at the same time, keeping your head tilted forward and down.
5. Repeat in other nostril.
6. If your healthcare provider tells you to use 2 sprays in each nostril, repeat Steps 2 and 4 above for the second spray in each nostril.



Figure 4

7. Breathe in gently, and do not tilt your head back after using ASTEPRO Nasal Spray. This will help to keep the medicine from going into your throat.
8. When you finish using ASTEPRO Nasal Spray, wipe the spray tip with a clean tissue or cloth. Put the safety clip and dust cover back on the bottle.

**To Clean the Spray Tip:**

1. If the spray tip opening is clogged, do not use a pin or pointed object to unclog the tip. Unscrew the spray pump unit from the bottle by turning it counter-clockwise (to the left). See Figure 5.
2. Soak only the spray pump unit in warm water. Squirt several times while holding it under water. Use the pumping action to clear the opening in the tip. See Figure 6.

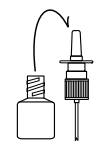


Figure 5

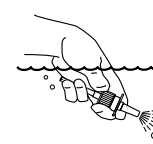


Figure 6

3. Let the spray pump unit air dry. Make sure it is dry before you put it back onto the bottle.
4. Put the spray pump unit back into the open bottle and tighten it by turning clockwise (to the right).

5. To keep the medicine from leaking out, use firm pressure when you put the pump back onto the bottle.

6. After cleaning, follow the instructions for priming.

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Manufactured by

MEDA Pharmaceuticals

MEDA Pharmaceuticals Inc.

Somerset, NJ 08873

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IN-023D6-03

Revised 10/08

**New ASTEPRO**

**NDC No.**

0037-0242-30

**How supplied**

One 30-mL bottle of ASTEPRO contains 200 metered sprays

**Order now to be ready for allergy season!**

Powerful efficacy

Improved tolerability

Rapid relief: Significant improvement in TNSS in as early as 30 minutes

- In one placebo-controlled study of 284 SAR patients conducted over 2 weeks, ASTEPRO administered 2 sprays per nostril bid demonstrated an onset of action vs placebo vehicle at 30 minutes and sustained efficacy vs placebo through the end of the 2-week study period.<sup>1</sup>
- In a second study of 343 SAR patients conducted over 2 weeks, ASTEPRO administered 2 sprays per nostril bid demonstrated an onset of action vs placebo vehicle at 240 minutes and sustained efficacy vs placebo through the end of the 2-week study period.<sup>2</sup>

*Rx Astepro  
1-2 sprays per nostril bid as directed.  
Refill 6 times*

**Important Safety Information**

- ASTEPRO (azelastine hydrochloride) Nasal Spray is indicated for the relief of the symptoms of seasonal allergic rhinitis in patients 12 years of age and older
- The most commonly reported adverse events were dose related (1 and 2 sprays per nostril respectively) and included bitter taste (6%-7%), epistaxis (2%-3%), headache (1%-3%), nasal discomfort (0%-1%), fatigue (0%-2%), and somnolence (1%-2%)
- Avoid engaging in hazardous occupations requiring complete mental alertness when taking ASTEPRO Nasal Spray
- Avoid concurrent use of alcohol or other central nervous system depressants with ASTEPRO Nasal Spray

References: 1. Data on file. Study MP430. Meda Pharmaceuticals Inc. 2. Data on file. Study MP438. Meda Pharmaceuticals Inc. 3. ASTEPRO [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; 2008.

Please see accompanying full Prescribing Information.

[astepro.com](http://astepro.com)



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**NEW Astepro™**  
(azelastine HCl)  
Nasal Spray, 137 mcg



Finally, relief for nasal allergy symptoms has turned **“PRO”**  
**INTRODUCING NEW ASTEPRO.**

**Powerful efficacy\***

- Significantly reduced symptoms of nasal congestion, runny nose, itchy nose, and sneezing vs placebo (P<.001)<sup>1</sup>

**Rapid relief\***

- Significant relief of Total Nasal Symptom Score (TNSS) in as early as 30 minutes (P<.05)<sup>1,2</sup>

**Improved tolerability\***

- 93% reported no bitter taste<sup>1,3</sup>
- 98% reported no somnolence<sup>1,3</sup>

\*Results based on 2 sprays per nostril bid.

**Order now to be ready for allergy season!**

**New ASTEPRO**

**NDC No.**

0037-0242-30

**How supplied**

One 30-mL bottle of ASTEPRO contains 200 metered sprays

**Point-of-sale coupon provides instant savings for eligible patients—available at [astepro.com](http://astepro.com)**

**NEW Astepro™**  
(azelastine HCl)  
Nasal Spray, 137 mcg



# ASTEPRO™ (azelastine hydrochloride) Nasal Spray

IN-023D6-03

Rev. 10/08

## HIGHLIGHTS OF PRESCRIBING INFORMATION

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

## ASTEPRO™ (azelastine hydrochloride) Nasal Spray Initial U.S. Approval: 1996

### INDICATIONS AND USAGE

ASTEPRO Nasal Spray is an H<sub>1</sub> receptor antagonist indicated for the relief of the symptoms of seasonal allergic rhinitis in patients 12 years of age and older. (1.1)

### DOSAGE AND ADMINISTRATION

For intranasal use only. Usual starting dosages:

- Seasonal allergic rhinitis: Adults and adolescents 12 years of age and older: 1 or 2 sprays per nostril twice daily (2.1)

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