

and evening (PM) rTNSS scores were summed for each day (maximum score of 24) and then averaged over the 14-day treatment period. (Table 2)

Table 2. Mean Change from Baseline in Reflective TNSS Over 2 Weeks* in Adults and Children ≥ 12 years with Seasonal Allergic Rhinitis						
Treatment (sprays per nostril twice daily)	n	Baseline LS Mean	Change from Baseline	Difference From Placebo		
				LS Mean	95% CI	P value
ASTEPRO Nasal Spray- two sprays	146	18.0	-5.0	-2.2	-3.2,-1.2	<0.001
Astelin Nasal Spray- two sprays	137	18.1	-4.2	-1.4	-2.4,-0.4	0.008
Placebo Vehicle- two sprays	138	18.1	-2.8			
ASTEPRO Nasal Spray- one spray	139	18.1	-4.2	-0.7	-1.7,0.3	0.181
Astelin Nasal Spray- one spray	137	18.1	-3.9	-0.4	-1.5,0.6	0.405
Placebo Vehicle- one spray	137	17.9	-3.5			

*Sum of AM and PM rTNSS for each day (Maximum score=24) and averaged over the 14 day treatment period

The efficacy of ASTEPRO Nasal Spray one spray per nostril twice daily is supported by two, 2-week, placebo controlled clinical trials with Astelin Nasal Spray in 413 patients with seasonal allergic rhinitis. In these trials, efficacy was assessed using the TNSS (described above). Astelin Nasal Spray demonstrated a greater decrease from baseline in the summed AM and PM rTNSS compared with placebo and the difference was statistically significant.

16 HOW SUPPLIED/STORAGE AND HANDLING

ASTEPRO (azelastine hydrochloride) Nasal Spray, 137 mcg, (NDC 0037-0242-30) is supplied as a package delivering 200 metered sprays in a high-density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit. FDA-approved patient labeling is also provided. The spray pump unit consists of a nasal spray pump fitted with a blue safety clip and a blue plastic dust cover. Net contents of the bottle is 30 mL (net weight 30 gm of solution).

The ASTEPRO (azelastine hydrochloride) Nasal Spray, 137 mcg, bottle contains 30 mg (1 mg/mL) of azelastine hydrochloride. After priming [see *Dosage and Administration* (2.2)], each spray delivers a fine mist containing a mean volume of 0.137 mL solution containing 137 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, even though the bottle is not completely empty. The bottle should be discarded after 200 sprays have been used.

Storage:

Store upright at controlled room temperature 20° - 25°C (68° - 77°F). Protect from freezing.

17 PATIENT COUNSELING INFORMATION

Patients should be instructed to use ASTEPRO Nasal Spray only as prescribed. For the proper use of the nasal spray and to attain maximum improvement, the patient should read and follow carefully the accompanying FDA-Approved Patient Labeling.

17.1 Common Adverse Reactions

Patients should be informed that treatment with ASTEPRO Nasal Spray may lead to adverse reactions, which include bitter taste, epistaxis, headache, and somnolence [see *Adverse Reactions* (6.1)].

17.2 Activities Requiring Mental Alertness

Somnolence has been reported in some patients taking ASTEPRO Nasal Spray. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness and motor coordination such as driving or operating machinery after administration of ASTEPRO Nasal Spray [see *Warnings and Precautions (5.1)*].

17.3 Concurrent Use of Alcohol and other Central Nervous System Depressants

Concurrent use of ASTEPRO 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 *Warnings and Precautions (5.1)*].

17.4 Priming

Patients should be instructed to prime the pump before initial use and when ASTEPRO Nasal Spray has not been used for 3 or more days [see *Dosage and Administration (2.2)*].

17.5 Keep Spray Out of Eyes

Patients should be instructed to avoid spraying ASTEPRO Nasal Spray into their eyes.

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PATIENT INFORMATION

ASTEPRO™ [*AS-ta-PRO*] (azelastine hydrochloride)
Nasal Spray

Important: For use in the nose only

Read this information carefully before you start using ASTEPRO Nasal Spray and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is ASTEPRO Nasal Spray?

- ASTEPRO Nasal Spray is a prescription medicine used to relieve symptoms of seasonal allergies in people age 12 and older.
- ASTEPRO Nasal Spray contains an antihistamine that may help reduce the nasal symptoms of rhinitis (inflammation of the lining of the nose): stuffy nose, runny nose, itching and sneezing.

It is not known if ASTEPRO Nasal Spray works and is safe in children under age 12.

What should I tell my healthcare provider before using ASTEPRO Nasal Spray?
Before using ASTEPRO Nasal Spray tell your healthcare provider about all your medical conditions, including if you are:

- allergic to any of the ingredients in ASTEPRO Nasal Spray. See the end of this leaflet for a complete list of ingredients in ASTEPRO Nasal Spray.
- pregnant, think you may be pregnant, or planning to become pregnant. It is not known if ASTEPRO Nasal Spray will harm your unborn baby.
- breastfeeding. It is not known if ASTEPRO Nasal Spray passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. ASTEPRO Nasal Spray and other medicines may affect each other, causing side effects.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider when you get a new medicine.

How should I use ASTEPRO Nasal Spray?

- ASTEPRO Nasal Spray is for use in your nose only. **Do not spray it into your eyes or mouth.**
- Use ASTEPRO Nasal Spray exactly as your healthcare provider tells you. **Do not** use more than your healthcare provider tells you.
- The usual dose of ASTEPRO Nasal Spray is 1 or 2 sprays in each nostril two times a day. Your healthcare provider will prescribe the dose that is right for you.
- Before you use ASTEPRO Nasal Spray for the first time, you will need to prime the bottle. See priming instructions at the end of this leaflet.
- Do not use ASTEPRO Nasal Spray if a fine mist is not seen after the initial priming sprays (6 sprays or less).
- Throw away your ASTEPRO Nasal Spray bottle after using 200 sprays. Even though the bottle may not be completely empty, you may not get the correct dose of medicine.
- **If a child accidentally swallows ASTEPRO Nasal Spray, get medical help or call a poison control center right away.**

What should I avoid while using ASTEPRO Nasal Spray?

ASTEPRO Nasal Spray can cause sleepiness:

- Do not drive a car, operate machinery or do dangerous activities after you use ASTEPRO Nasal Spray.
- Avoid drinking alcohol or taking other medicines that may also cause sleepiness while using ASTEPRO Nasal Spray.

What are the possible side effects of ASTEPRO Nasal Spray?

Side effects of ASTEPRO Nasal Spray include:

- unusual taste (bitter or sweet)
- nosebleeds
- headache
- fatigue
- sleepiness

437 Tell your healthcare provider if you have any side effect that bothers you or that does not
438 go away. These are not all of the possible side effects of ASTEPRO Nasal Spray. For
439 more information, ask your healthcare provider or pharmacist.

440

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

443

444 **How should I store ASTEPRO Nasal Spray**

445 • Keep ASTEPRO Nasal Spray upright at 68° to 77°F (20° to 25°C).

446 • Do not freeze ASTEPRO Nasal Spray.

447

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

449

450 **General information about ASTEPRO Nasal Spray.**

451

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

456

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

461

462 For more information, go to www.Astepro.com or call 1-800-598-4856.

463

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

465 Active ingredient: azelastine hydrochloride

466

467 Inactive ingredients: sorbitol, sucralose, hypromellose, sodium citrate, edetate disodium,
468 benzalkonium chloride and purified water.

469

470 **Patient Instructions for Use**

471

For use in your nose only

472

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

475

476 **For the correct dose of medicine:**

477 • Use ASTEPRO Nasal Spray exactly as prescribed by your healthcare provider.

478 • Keep your head tilted downward when spraying into your nostril.

479 • Change nostrils each time you use the spray.

480 • **Breathe gently and do not tip your head back after using the spray.** This will keep
481 the medicine from running down into your throat. You may get a bitter taste in your

482 mouth.

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484 Follow the instructions below to use your ASTEPRO Nasal Spray pump.

485 See Figure 1.

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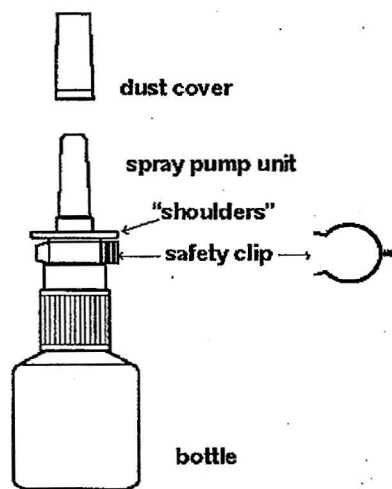


Figure 1

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.

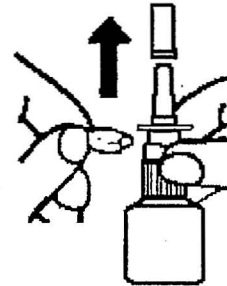


Figure 2

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.

Now your pump is primed and ready to use.

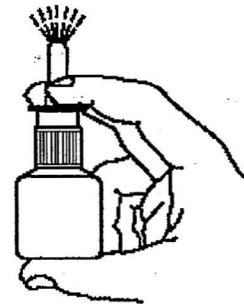


Figure 3

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 $\frac{1}{4}$ to $\frac{1}{2}$ 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.



Figure 4

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.
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.

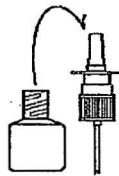


Figure 5

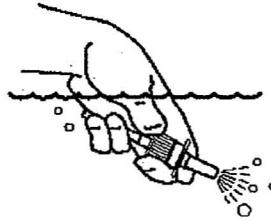


Figure 6

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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