

PATIENT INFORMATION
ASTEPRO [AS-ta-PRO]
(azelastine hydrochloride)
Nasal Spray 0.1% and 0.15%

Important: For use in your 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 information 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 0.1% and 0.15% is a prescription medicine used to relieve symptoms of seasonal allergies in people age 12 and older.
- ASTEPRO Nasal Spray 0.15% is also used to relieve symptoms of year-round 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 or effective in children younger than 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 to be sprayed 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.
- Read the Patient Instructions for Use at the end of this information for detailed instructions about how to use ASTEPRO Nasal Spray.
- 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 in the detailed Patient Instructions for Use.
- Do not use ASTEPRO Nasal Spray unless you see a fine mist after you do the priming sprays.
- Throw away your ASTEPRO Nasal Spray 0.1% bottle after using 200 sprays. Even though the bottle may not be completely empty, you may not get the correct dose of medicine.
- Throw away your ASTEPRO Nasal Spray 0.15% 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 cause you to feel sleepy 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)
- nose pain or discomfort
- nosebleeds
- headache
- fatigue
- sleepiness
- sneezing

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.
- Do not use ASTEPRO Nasal Spray after the expiration date "EXP" on the medicine label and box.

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

General information about ASTEPRO Nasal Spray.

Medicines are sometimes prescribed for conditions other than those mentioned in patient information. 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 patient information 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 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, benzaikonium chloride, and purified water.

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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.

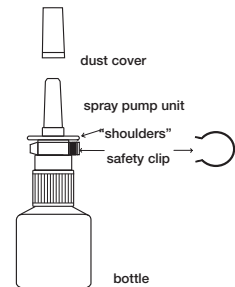


Figure 1

Before you use ASTEPRO Nasal Spray 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.
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. This should happen in 6 sprays or less. See Figure 3.

Now your pump is primed and ready to use.

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.



Figure 2



Figure 3

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 through 5 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.



Figure 4

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.

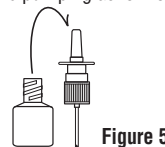


Figure 5

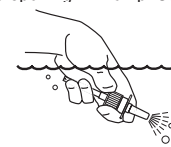


Figure 6

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.

Manufactured by:
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