



PATIENT INFORMATION

Azelastine Hydrochloride Nasal Solution (Nasal Spray), 0.1% (137 mcg per spray) (a-ZEL-as-teen HYE-droe-KLOR-ide)

Important: For use in your nose only.

What is azelastine hydrochloride nasal solution?

- Azelastine hydrochloride nasal solution is a prescription medicine used to treat symptoms of seasonal allergic rhinitis in people age 5 and older and vasomotor rhinitis in people age 12 and older.
- Azelastine hydrochloride nasal solution may help to reduce your nasal symptoms including stuffy nose, runny nose, itching and sneezing.

It is not known if azelastine hydrochloride nasal solution is safe and effective in children with seasonal allergic rhinitis under 5 years of age or in children with vasomotor rhinitis under 12 years of age.

What should I tell my healthcare provider before using azelastine hydrochloride nasal solution?

Before using azelastine hydrochloride nasal solution, tell your healthcare provider if you are:

- allergic to any of the ingredients in azelastine hydrochloride nasal solution. See the end of this leaflet for a complete list of ingredients in azelastine hydrochloride nasal solution.
- pregnant, or plan to become pregnant
- breastfeeding, or plan to breastfeed. It is not known if azelastine hydrochloride passes into your breast milk. You and your healthcare provider should decide if you will use azelastine hydrochloride nasal solution if you plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Azelastine hydrochloride nasal solution and other medicines may affect each other, causing side effects.

How should I use azelastine hydrochloride nasal solution?

- Read the **Instructions for Use** at the end of this leaflet for information about the right way to use azelastine hydrochloride nasal solution.
- Spray azelastine hydrochloride nasal solution in **your nose only. Do not spray it into your eyes or mouth.**
- Use azelastine hydrochloride nasal solution exactly as your healthcare provider tells you to use it.
- **Do not** use more than your healthcare provider tells you.
- Throw away your azelastine hydrochloride nasal solution bottle after using 200 sprays. Even though the bottle may not be completely empty, you may not get the correct dose of medicine.
- If you use too much or a child accidentally swallows azelastine hydrochloride nasal solution, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while using azelastine hydrochloride nasal solution?

Azelastine hydrochloride nasal solution can cause sleepiness:

- **Do not** drive, operate machinery, or do other dangerous activities until you know how azelastine hydrochloride nasal solution affects you.
- **Do not** drink alcohol or take other medicines that may cause you to feel sleepy while using azelastine hydrochloride nasal solution. It may make your sleepiness worse.

What are the possible side effects of azelastine hydrochloride nasal solution?

The most common side effects of azelastine hydrochloride nasal solution include:

- unusual bitter taste
- headache
- sleepiness
- nose burning, pain or discomfort
- runny nose
- scratchy or sore throat
- nosebleeds
- inflammation or swelling of the sinuses
- sneezing
- nausea
- dry mouth
- fatigue
- dizziness
- weight increase

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 solution. 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 solution?

- Keep azelastine hydrochloride nasal solution upright at 20° to 25°C (68° to 77°F).
- Do not freeze azelastine hydrochloride nasal solution.
- Do not use azelastine hydrochloride nasal solution after the expiration date “Exp” on the medicine label and box.

Keep azelastine hydrochloride nasal solution and all medicines out of reach of children.

General information about the safe and effective use of azelastine hydrochloride nasal solution.

Medicines are sometimes prescribed for conditions other than those listed in a Patient Information leaflet. Do not use azelastine hydrochloride nasal solution for a condition for which it was not prescribed. Do not give azelastine hydrochloride nasal solution 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 solution. 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 solution that is written for health professionals.

For more information call 1-800-818-4555.

What are the ingredients in azelastine hydrochloride nasal solution?

Active ingredient: azelastine hydrochloride
Inactive ingredients: benzalkonium chloride 50% solution (250 mcg/mL), edetate disodium, hypromellose, citric acid anhydrous, dibasic sodium phosphate, sodium chloride, and water for injection.

Instructions for Use

Azelastine Hydrochloride Nasal Solution (Nasal Spray), 0.1% (137 mcg per spray) (a-ZEL-as-teen HYE-droe-KLOR-ide)

Important: For use in your nose only.

For the correct dose of medicine:

- 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.

Figure A identifies the parts of your azelastine hydrochloride nasal solution pump

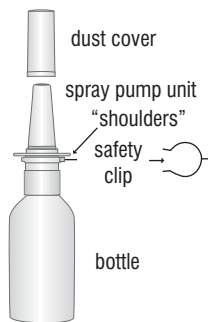


Figure A

Before you use azelastine hydrochloride nasal solution for the first time, you will need to prime the bottle.

Priming your azelastine hydrochloride nasal solution

Remove the blue dust cover over the tip of the pump and the blue safety clip just under the "shoulders" of the pump (See Figure B).

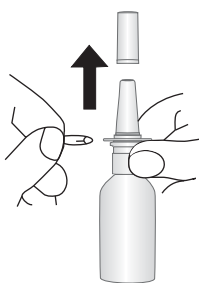


Figure B

Hold the bottle upright with 2 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 (See Figure C).
- 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 pump is not working correctly and you may have nasal discomfort.
- This should happen in 4 sprays or less.

Now your pump is primed and ready to use.



Figure C

- **Do not** use azelastine hydrochloride nasal solution unless you see a fine mist after you do the priming sprays. If you do not see a fine mist, clean the tip of the spray nozzle. See the "Cleaning the Spray Tip of your azelastine hydrochloride nasal solution" section below.
- If you do not use azelastine hydrochloride nasal solution for 3 or more days, you will need to prime the pump with 2 sprays or until you see a fine mist.

Using your azelastine hydrochloride nasal solution

Step 1. Blow your nose to clear your nostrils.

Step 2. Keep your head tilted downward toward your toes.

Step 3. Place the spray tip about ¼ inch to ½ inch into 1 nostril. Hold bottle upright and aim the spray tip toward the back of your nose (See Figure D).

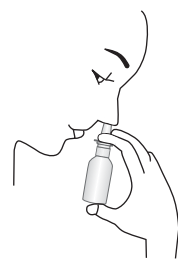


Figure D

Step 4. Close your other nostril with a finger. Press the pump 1 time and sniff gently at the same time, keeping your head tilted forward and down (See Figure E).



Figure E

Step 5. Repeat Step 3 and Step 4 in your other nostril.

Step 6. If your healthcare provider tells you to use 2 sprays in each nostril, repeat Steps 2 through 4 above for the second spray in each nostril.

Step 7. Breathe in gently, and **do not tilt your head back** after using azelastine hydrochloride nasal solution. This will help to keep the medicine from going into your throat.

Step 8. When you finish using your azelastine hydrochloride nasal solution, wipe the spray tip with a clean tissue or cloth. Put the safety clip and dust cover back on the bottle.

Cleaning the Spray Tip of your azelastine hydrochloride nasal solution

- 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 to the left (counterclockwise) (See Figure F).
- Soak only the spray pump unit in warm water. Squirt the spray unit several times while holding it under water. Use the pumping action to clear the opening in the tip (See Figure G).

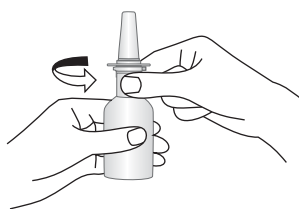


Figure F

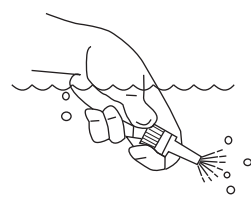


Figure G

- Let the spray pump unit air dry. Make sure it is dry before you put it back onto the bottle.
- Put the spray pump unit back into the open bottle and tighten it by turning clockwise (to the right).
- To keep the medicine from leaking out, use firm pressure when you put the pump back onto the bottle.
- After cleaning, follow the instructions for priming.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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