

**AZELASTINE HYDROCHLORIDE- azelastine hydrochloride spray, metered**  
**Allegiant Health**

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**478 - Nasal Spray Azelastine Hydrochloride**

**Active ingredient(s)**

Azelastine hydrochloride 205.5 mcg (equivalent to 187.6 mcg azelastine)

**Purpose**

Antihistamine

**Use(s)**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

**Warnings**

Only for use in the nose. Do not spray in eyes or mouth.

**Do not use if you have**

if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you**

- have had recent nose ulcers or nose surgery
- have had nose injury that has not healed

**When using this product**

- drowsiness may occur
  - avoid alcoholic drinks
  - alcohol, sedatives, and tranquilizers may increase drowsiness
  - be careful when driving a motor vehicle or operating machinery
- you may get a bitter taste in your mouth. To help avoid this, tilt your head downward while spraying.
- nasal discomfort or sneezing may occur right after use
- do not share this bottle with anyone else as this may spread germs

**Stop use and ask a doctor if**

- an allergic reaction, such as a skin rash, to this product occurs
- you have severe or frequent nosebleeds

**If pregnant or breastfeeding,**

ask a health professional before use.

**Keep out of reach of children**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- Read the User Guide for how to:
  - prime the bottle before first use
  - use the spray
  - prime bottle again if not used for 3 or more days
  - clean the spray nozzle if it gets clogged

adults and children 12 years and older	This product may be used either once or twice a day: <ul style="list-style-type: none"><li>• once daily: use 2 sprays in each nostril;OR</li><li>• twice daily: use 1 or 2 sprays in each nostril every 12 hours</li><li>• do not use more than 4 sprays in each nostril in a 24 hour period</li></ul>
children 6 years to 11 years	<ul style="list-style-type: none"><li>• an adult should supervise use</li><li>• 1 spray in each nostril every 12 hours</li><li>• do not use more than 2 sprays in each nostril in a 24 hour period</li></ul>
children under 6 years	do not use

**Other information**

- store between 20°C to 25°C (68°F to 77°F). Protect from freezing
- keep this carton and the enclosed User Guide for important information
- do not use if sealed package is torn or opened

**Inactive ingredients**

benzalkonium chloride, edetate disodium dihydrate, hypromellose, purified water, sodium citrate (dihydrate), sorbitol, sucralose

**Questions/Comments**

Call **1-888-952-0050**

(Monday-Friday 9 AM – 5 PM EST)

**Principal Display Panel**

Health **AzZ**<sup>®</sup> NDC 69168-478-63

**ALLERGY RELIEF  
NASAL SPRAY**

Azelastine Hydrochloride | 205.5 mcg per spray

ANTI-HISTAMINE NASAL SPRAY

**120 Metered Sprays**  
0.78 fl. oz. (23 mL)

**24 HOUR**

**Important: Read and keep the carton closed. Do not use if you are pregnant or breastfeeding. Do not use if you are taking other prescription drugs. Do not use if you are taking other allergy medications. Do not use if you are taking other medications. Do not use if you are taking other drugs. Do not use if you are taking other products. Do not use if you are taking other supplements. Do not use if you are taking other vitamins. Do not use if you are taking other minerals. Do not use if you are taking other herbs. Do not use if you are taking other natural products. Do not use if you are taking other dietary supplements. Do not use if you are taking other nutraceuticals. Do not use if you are taking other botanicals. Do not use if you are taking other phytochemicals. Do not use if you are taking other phytonutrients. Do not use if you are taking other phytoestrogens. Do not use if you are taking other phytoalexins. Do not use if you are taking other phytochemicals. Do not use if you are taking other phytonutrients. Do not use if you are taking other phytoestrogens. Do not use if you are taking other phytoalexins.**

Children under 6 years: Do not use. Keep out of reach of children. Only for use in the nose. Do not use if you are pregnant or breastfeeding. Drowsiness may occur. Avoid alcohol. Alcohol may increase drowsiness. Be careful when driving a motor vehicle. Store between 20°C to 25°C (68°F to 77°F). Questions or comments? 1-888-4ALLEGANT. Mfg for: Allegiant Health, Deer Park, NY 11729

Azelastine hydrochloride label

Health **AzZ**<sup>®</sup>  
**ALLERGY RELIEF  
NASAL SPRAY**  
Azelastine Hydrochloride | 205.5 mcg p

Health **AzZ**<sup>®</sup>  
\*Compare to the active ingredient in

**ALLERGY RELIEF  
NASAL SPRAY**

Azelastine Hydrochloride  
205.5 mcg per spray

Free From: • Steroid  
• Alcohol  
• Fragrance

ANTI-HISTAMINE NASAL SPRAY  
FULL PRESCRIPTION STRENGTH

Up to 24 Hour Relief of:

- Runny Nose
- Nasal Congestion
- Itchy Nose
- Sneezing

Up to 24 Hour Relief of:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose

**120 Metered Sprays**  
0.78 fl. oz. (23 mL)

**Drug Facts (continued)**

**Directions**

- Read the User Guide for how to:
- prime the bottle before first use
- use the spray
- prime the bottle again if not used for 3 or more days
- clean the spray nozzle if it gets clogged

**adults and children 12 years and older**

This product may be used either once or twice a day:

- once daily: use 2 sprays in each nostril; OR
- twice daily: use 1 or 2 sprays in each nostril every 12 hours
- do not use more than 4 sprays in each nostril in a 24-hour period

**children 6 years to 11 years**

- an adult should supervise use
- 1 spray in each nostril every 12 hours
- do not use more than 2 sprays in each nostril in a 24-hour period

**children under 6 years**

do not use

**Other Information**

- store between 20°C to 25°C (68°F to 77°F). Protect from freezing.
- keep this carton and the enclosed User Guide for important information
- do not use if sealed package is torn or opened

**Inactive Ingredients**

bentalkonium chloride, sodium chloride, sodium citrate, purified water, sodium citrate dihydrate, hypromellose, purified water, sodium citrate dihydrate, sorbitol, sucralose

**Questions or comments?**

Call toll free 1-888-952-8800, Monday through Friday 9AM - 5PM EST

**INDOOR & OUTDOOR Allergy Relief**

\*This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark of Aspirin®.

Made in Canada

Manufactured for:  
Allegiant Health  
Deer Park, NY 11729

LB2300 R0325

3 69168 478

Azelastine hydrochloride carton



467856

## Azelastine Hydrochloride Nasal Spray

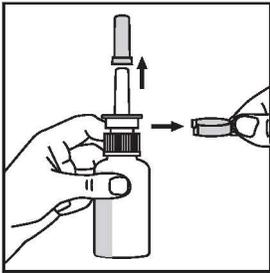
**205.5 mcg per spray**

**HOW TO START GETTING STEROID-FREE ALLERGY RELIEF RIGHT NOW**

This User Guide will give you detailed directions on how to prime the bottle, use the spray, and how to clean a clogged nozzle. Keep this User Guide as it contains important information.

**GET THE BOTTLE READY**

Remove the dust cover over the tip of the bottle and the safety clip.



**PRIME THE BOTTLE**

**WHEN TO PRIME**

- Before you use azelastine hydrochloride nasal spray for the first time
- If you have not used azelastine hydrochloride nasal spray for 3 or more days
- After you clean a clogged nozzle

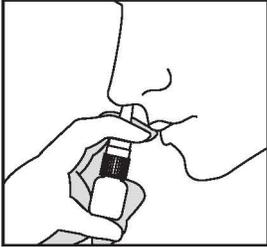
**HOW TO PRIME**

- Aim bottle away from face.
- Hold bottle as shown and pump until a fine mist appears.
- If a fine mist does not appear after 6 sprays, your nozzle may be clogged. Please see "How to Clean a Clogged Nozzle" section.



**STEP 2**  
Tilt your head downward toward your toes.

**STEP 3**  
Hold bottle with thumb under bottle and spray nozzle between fingers.



**TILT HEAD DOWNWARD**

**STEP 4**  
Close one nostril.

**STEP 5**  
Put the spray tip about 1/4 inch to 1/2 inch into the other nostril. Hold bottle upright and aim the spray tip toward the back of your nose.

**STEP 6**  
While sniffing gently, press the pump once or twice (according to dosing directions found in Table 1). Repeat Steps 4, 5 and 6 in other nostril.



**HOLD ONE NOSTRIL SHUT**

**STEP 7**  
Do not tilt your head back immediately after using azelastine hydrochloride nasal spray. This will help to keep the medicine from going into your throat, which may cause a bitter taste.

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

**FOR USE IN CHILDREN**  
An adult should supervise use. (See Steps 1 through 6).

**SELECT THE DOSE**

**DIRECTIONS**  
Do not use more than directed.

<b>TABLE 1</b>	
adults & children 12 years and older	This product may be used either once or twice a day: <ul style="list-style-type: none"> <li>■ <b>once daily:</b> use 2 sprays in each nostril; <b>OR</b></li> <li>■ <b>twice daily:</b> use 1 or 2 sprays in each nostril every 12 hours</li> </ul> <b>do not use more than 4 sprays</b> in each nostril in a 24-hour period
children 6 years to 11 years	<ul style="list-style-type: none"> <li>■ an adult should supervise use</li> <li>■ 1 spray in each nostril every 12 hours</li> </ul> <b>do not use more than 2 sprays</b> in each nostril in a 24-hour period
children under 6 years	do not use

**HOW TO USE**

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

**STEP 1**  
Blow your nose to clear your nostrils.

**IMPORTANT INFORMATION FOR USE**  
Remember, when using this product:  
 • Drowsiness may occur.  
 > Avoid alcoholic drinks.

216 mm

180 mm

27 mm

## Azelastine hydrochloride insert

180 mm

27 mm

216 mm

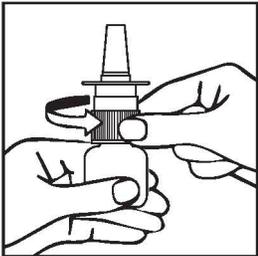
• Alcohol, sedatives, and tranquilizers may increase drowsiness.  
• Be careful when driving a motor vehicle or operating machinery.

\*In clinical trials, drowsiness was observed in less than 4% of patients taking azelastine hydrochloride nasal spray.

**HOW TO CLEAN A CLOGGED NOZZLE**

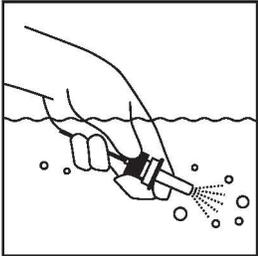
If you cannot get your azelastine hydrochloride nasal spray to spray a fine mist, the nozzle may be clogged.  
Don't try to unplug the nozzle with a pin or sharp object—that can damage it.

- Unscrew the spray pump unit from the bottle by turning it to the left (counter-clockwise).
- **Keep open bottle out of reach of children.**



UNSCREW PUMP UNIT

- Fill a bowl or container with warm water. Soak only the spray pump unit in the warm water. Pump the nozzle several times while holding it under the water to clear the clog.



PUMP NOZZLE WHILE HOLDING IT UNDERWATER

Let the spray pump unit air dry before putting it back on.  
Tightly screw pump unit back on the open bottle by turning clockwise (to the right).

- After cleaning, follow the instructions for priming.

**QUESTIONS OR COMMENTS?**  
1-888-952-0050, Monday-Friday, 9AM-5PM EST

**Manufactured for:**  
Allegiant Health  
Deer Park, NY 11729  
1B2311 R0425

Revised: November 2021

**Azelastine hydrochloride insert**

**AZELASTINE HYDROCHLORIDE**

azelastine hydrochloride spray, metered

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-478
<b>Route of Administration</b>	NASAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AZELASTINE HYDROCHLORIDE</b> (UNII: 0L591QR10I) (AZELASTINE - UNII:ZQI909440X)	AZ ELASTINE HYDROCHLORIDE	205.5 ug

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69168-478-63	1 in 1 CARTON	09/22/2025	
1		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:69168-478-02	2 in 1 CARTON	09/22/2025	
2		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA216421	05/02/2025	

**Labeler** - Allegiant Health (079501930)