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: • 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 spraysin 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 spraysin 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

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

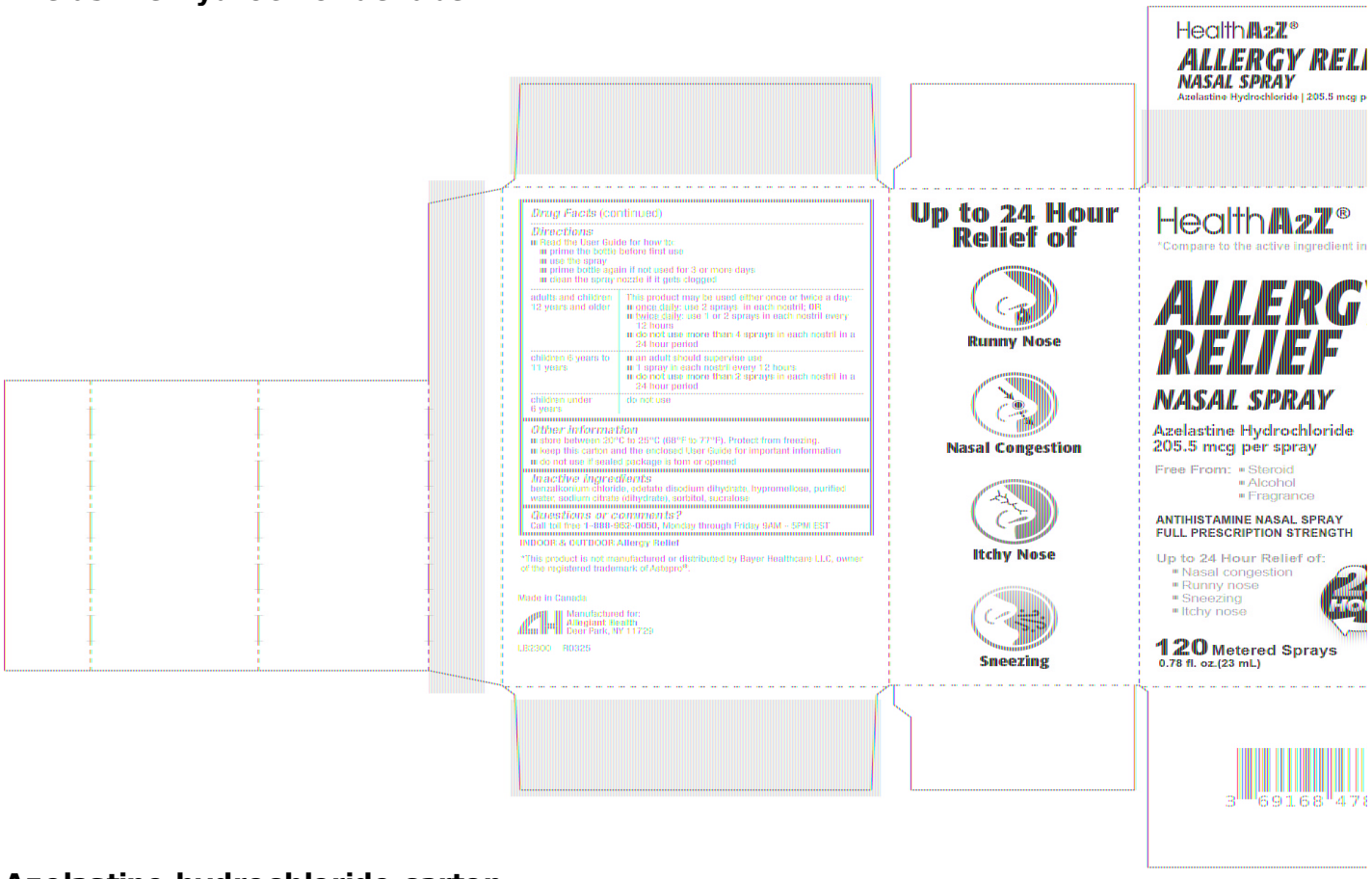
Questions/Comments

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

(Monday-Friday 9 AM – 5 PM EST)

Principal Display Panel

Azelastine hydrochloride label



Azelastine hydrochloride carton

180 mm

27 mm

216 mm

467856

Azelastine Hydrochloride Nasal Spray

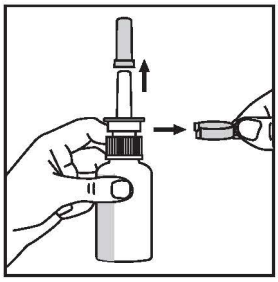
205.5 mcg per spray

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.

HOW TO USE

Important: For use in your nose only

STEP 1
Blow your nose to clear your nostrils.

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 ¼ inch to ½ 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 8).

SELECT THE DOSE

DIRECTIONS
Do not use more than directed

TABLE 1

adults & 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

IMPORTANT INFORMATION FOR USE
Remember, when using this product:

- Drowsiness may occur*
  - › Avoid alcoholic drinks.

Azelastine hydrochloride insert

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

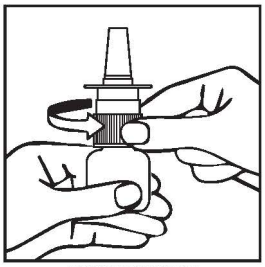
*In clinical trials, drowsiness was observed in less than 4% of patients taking azelastine hydrochloride nasal spray.

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.

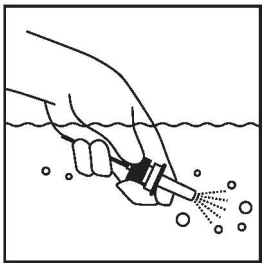
Don't try to unclog the nozzle with a pin or sharp object—that can damage it.

- 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

LB2311 R0425

Revised: November 2021

180 mm

27 mm

216 mm

Azelastine hydrochloride insert

AZELASTINE HYDROCHLORIDE

azelastine hydrochloride spray, metered

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-478
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AZELASTINE HYDROCHLORIDE (UNII: 0L591QR10I) (AZELASTINE - UNII:ZQI909440X)	AZELASTINE HYDROCHLORIDE	205.5 ug

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-478-63	120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	05/02/2025	

Marketing Information

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

Labeler - Allegiant Health (079501930)

Revised: 5/2025 Allegiant Health